



# Biotech Daily

Friday May 24, 2024

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market fell 1.08 percent on Friday May 24, 2024, with the ASX200 down 84.2 points to 7,727.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 10 were down, nine traded unchanged and four were untraded. All three Big Caps fell.

Medadvisor was the best, up 3.5 cents or 9.0 percent to 42.5 cents, with three million shares traded. Next Science climbed six percent; Clarity was up 5.3 percent; Paradigm improved 4.1 percent; Amplia, Medical Developments, Proteomics and Universal Biosensors were up three percent or more; 4D Medical, Emvision, Orthocell and Polynovo rose more than two percent; Alcidion, Clinuvel, Cynata and Nova Eye were up more than one percent; with Pro Medicus up by 0.1 percent.

Avita led the falls, down 16 cents or 6.0 percent to \$2.50, with 608,800 shares traded. Starpharma fell 4.35 percent; Actinogen, Immutep, Nanosonics and Resmed were down more than three percent; Impedimed shed 2.4 percent; Imugene and Percheron were down more than one percent; with Cochlear, CSL, Mesoblast and Telix down by less than one percent.

## [DR BOREHAM'S CRUCIBLE: PROTEOMICS INTERNATIONAL LABORATORIES](#)

**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 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 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**

Based on 5,000 patient samples, in multiple four-year studies, the company's key claim is that Promarker D can predict diabetic kidney disease up to four years earlier than standard-of-care, enabling doctors to prescribe therapies earlier.

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). With 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. 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 with diagnosis taking an average 7.5 years and requiring a laparoscopy, costing \$US2,000 to \$US3,000, and involving 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.***

## [CYCLOPHARM](#)

Cyclopharm says it hopes to raise \$22 million at \$1.42 a share in a \$20 million institutional placement and \$2 million share purchase plan.

Cyclopharm said the \$1.42 issue price was a 13.9 percent discount to yesterday's last traded price of \$1.65.

The company said the funds would be used for "expansion and growth of Technegas in the US ... expanding the use of Technegas beyond the pulmonary embolism market, ongoing research and development activities, product and systems enhancement, and working capital".

Cyclopharm said the share plan was for holders in Australia, New Zealand and the UK, who could apply for up-to \$30,000 worth of shares, each.

The company said the share purchase plan had a record date of May 23, would open on May 31 and close on June 21, 2024.

Cyclopharm said Macquarie Capital and Bell Potter were lead managers to the raise.

Earlier, the company requested a trading halt for the capital raising.

Trading will resume on May 27, 2024, or on an earlier announcement.

Cyclopharm last traded at \$1.65.

## [ADHERIUM](#)

Adherium says Astrazeneca will pay it \$1.1 million in a three-year contract to use its Hailie Smartinhaler device for a clinical trial of its inhaler medications.

Adherium said Astrazeneca's inhaled drug use would be recorded and transferred through Hailie and it would supply Smartinhalers, the Smartinhaler App and the associated Platform for the trial.

Adherium chief executive officer Dr Paul Mastoridis said the "agreement underscores Adherium's strategic commitment to enhancing patient care through advanced technology".

"Our Hailie platform is designed to ensure precise monitoring and support for patients with respiratory diseases, facilitating the pursuit of tailored therapy," Dr Mastoridis said.

Adherium was up 0.4 cents or 21.05 percent to 2.3 cents with 30.4 million shares traded.

## [AUSTCO HEALTHCARE](#)

Austco says the Charlotte, North Carolina-based Premier Inc it has granted it a national group purchasing agreement for its nurse call hospital management system in the US.

Austco said Premier was a healthcare improvement company with an alliance of about 4,400 US hospital members and 250,000 other healthcare provider members.

The company said the agreement allowed Premier members "to take advantage of special pricing and terms pre-negotiated by Premier".

Austco said the agreement did not guarantee immediate revenue but was "an important step in promoting the Austco brand as a leading nurse call provider in the US and provides immediate reach to the alliance of hospitals and healthcare providers".

The company did not disclose the commercial terms of the agreement.

Austco chief executive officer Clayton Astles said the agreement "underpins Austco's reputation for delivering innovative, high-quality clinical communication solutions to healthcare providers nationwide".

"We're excited to offer Premier members access to our industry-leading technology designed to enhance patient care and streamline operational efficiency," Mr Astles said.

Austco was up half a cent or 2.6 percent to 19.5 cents.

### PYC THERAPEUTICS

PYC says it has received US Food and Drug Administration (FDA) orphan drug designation for PYC-001 for autosomal dominant optic atrophy (ADOA).

PYC said orphan drug status was given to drug candidates designed to treat rare disease and included tax credits for qualified clinical trials, exemptions from some regulatory fees and the potential for seven years of market exclusivity post-approval.

The company said it expected to begin a phase I clinical trial of PYC-001 for autosomal dominant optic atrophy “later this year”, subject to successful regulatory engagement.

PYC was unchanged at 12 cents with 8.6 million shares traded.

### PYC THERAPEUTICS

PYC says it has established an unmarketable parcels facility for holders of shares worth less than \$500, or 10.5 cents each, at the record date of May 22, 2024.

PYC said that an unmarketable parcel was 4,761 shares or fewer and shareholders would be able to sell shares without incurring brokerage or handling costs.

The company said the unmarketable parcels facility would help reduce administrative costs, including printing and mailing costs and share registry expenses associated with maintaining a large number of small shareholdings.

### RADIOPHARM THERANOSTICS

Radiopharm chair Paul Hopper says his substantial 94,221,428 share-holding in the company has been diluted from 28.68 percent to 20.5 percent via the issue of shares.

Earlier this year, Radiopharm said it had an up-to \$12.5 million draw-down equity facility with New York’s Lind Partners (BD: Feb 6, Apr 15, 2024).

Radiopharm was unchanged at 3.3 cents.

### RADIOPHARM THERANOSTICS

The Hong Kong-based Nanomab Technology Ltd says its 28,295,131 share-holding in Radiopharm was diluted from 8.6 percent to 6.1 percent (see above).

### OSTEOPORE

The Singapore-based Edge Capital Fund says that it has become substantial in Osteopore with 7,461,000 shares or 6.85 percent.

Edge Capital said that on March 14, 2024 it bought 1,000 shares for \$355, or 35.5 cents a share, and on May 8, 2024 bought 7,460,000 shares for \$216,340, or 2.9 cents a share.

Osteopore fell 0.1 cents or 1.4 percent to 6.9 cents with 2.5 million shares traded.

### PHARMAUST

Pharmaust says that it has appointed Stefan Ross as company secretary, effective from May 24, 2024.

Pharmaust was unchanged at 18 cents.