



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Rhythm Biosciences

**By TIM BOREHAM**

**ASX code:** RHY

**Share price:** \$1.55

**Shares on issue:** 214,090,282

**Market cap:** \$331.8 million

**Chief executive officer:** Glenn Gilbert

**Board:** Otto Buttula (executive chair), Mr Gilbert, Dr Trevor Lockett, Lou Panaccio, Eduardo Vom, Dr Rachel David

**Financials (March quarter 2022):** revenue nil, cash burn \$1.96 million, cash of \$9.94 million

**Major shareholders:** Otto Buttula 13.6%, Michelle Wing 9.27%, Loumea Investments 4.9%, Sarah Cameron 3.1%.

As with your columnist, plenty of other Australians aged between 50 and 74 are suffering from 'poo-crastination'.

Every two years, anyone in that cohort receives a bowel cancer test kit from the Federal Health Department, which requires them to harvest two faecal samples over two days.

Suddenly cleaning the oven or doing the ironing become far more compelling tasks.

The Faecal Immunochemical Test - FIT - is provided as part of the National Bowel Screening Program - and is FREE. Yet only about 40 percent of recipients carry out the fiddly assays and return the samples.

Three out of 10 testees advised to seek a colonoscopy - the more definitive way to detect bowel tumours - do not do so. That's a pity because bowel cancer is one of the most treatable cancers if detected early.

"Many people simply don't take the test for fear of an unnecessary colonoscopy, unpleasantness, difficulty or for religious or cultural reasons," Rhythm chief executive Glenn Gilbert says.

### **So, is there a better way?**

In concert with the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Rhythm Biosciences has been beavering away at a blood test alternative, which is intended to be more accurate and more palatable than the poo test.

After years of development, things are happening.

In November 2021, the company won Conformité Européenne (CE) mark approval to market the test in the European Union, while in January this year, approval was extended to Britain and Northern Ireland.

In May, the company filed an approval application with the Australian Therapeutics Goods Administration.

"It's been a very, very, very busy time," says Mr Gilbert.

### **About Rhythm**

Colostat is based on intellectual property developed by the venerable CSIRO, which toyed around with the know-how for 13 years before hiving off the tech to Rhythm.

Rhythm listed on the ASX on December 7, 2017 after raising \$9 million at 20 cents apiece.

Rhythm has had a number of management reshuffles along the way. The company was first helmed by CSIRO veteran Dr Trevor Lockett, who moved to technical director in favor of then chief operating officer Mr Gilbert.

In November 2019, financial services entrepreneur Otto Buttula replaced Shane Tanner as chair. In December 2021, Mr Buttula was elevated to executive chair, while Mr Gilbert was promoted to the board (that is, he became managing-director).

Mr Buttula said the reshuffle reflected the "strong and symbiotic" relationship between the pair. In other words, they move to the same rhythm.

## **Key (Colo)stats**

The FIT tests also have a fundamental drawback, in that they only detect blood in the stool, rather than more definitive bowel cancer biomarkers.

Blood could be present in the stools for other reasons, such as bleeding haemorrhoids.

The idea is that the Colostat test can be delayed during a routine doctor check-up for a patient of any age, using the same blood sample used for standard assays such as cholesterol or blood sugar tests.

Bear in mind that bowel cancer is the most common cancer among 25 to 29-year-olds.

Colostat could also be used as a triage tool, to prioritize patients with a positive stool test for a follow-up colonoscopy bearing in mind limited hospital and clinic resources.

The testing platform could also be expanded to low-cost tests for detecting breast, cervical, lung, pancreatic and gastric cancers - possibly on the one test panel.

Last week, Rhythm completed a biomarker review in view of expanding its platform to these cancers and has engaged Agile Biolabs - an arm of Australian pathology giant Healius (formerly Primary Health Care) - to accelerate development.

## **A rhythm method you can rely on**

After some pandemic delays, in April this year Rhythm completed a full-blown Australian clinical trial - study seven - to support the approval submissions.

The trial collected 989 samples across 12 sites, 737 of which were included in the final analysis.

The trial met primary and secondary endpoints, showing 81 percent sensitivity and 91 percent specificity.

Sensitivity is the ability to correctly identify patients with a disease, while specificity is the ability to identify those without the disease. And rest assured, this is the only time you will hear that the Rhythm method is the most reliable ...

The trial tested Colostat's efficacy relative to a colonoscopy in detecting colorectal cancers and advanced adenomas (benign tumors).

The clinical trial demonstrated the assay was 35 percent more accurate than the FIT and was higher than the market-standard FIT for detecting advanced adenomas when compared head-to-head.

Initially based at Adelaide's Lyell McEwen Hospital, the trial was expanded to three Melbourne sites (Monash Health, Royal Melbourne Hospital and The Alfred).

But to avoid the lockdown delays in the Covid capital, the company signed up additional sites in New South Wales, Queensland and Western Australia.

Mr Gilbert says investors may not have appreciated the “robustness” of the trial, which involved participants taking the poo test and the Colostat blood test and then undergoing a colonoscopy as planned.

The patient samples are augmented with blinded samples from patients known to have bowel cancer.

## **Finances and performance**

Rhythm is yet to pocket a cent in revenue, but expects to be doing so by the end of this year.

In the meantime, Rhythm is well funded, with almost \$10 million in the bank - enough to take it to the revenue-producing stage.

In January, the company raised \$6.5 million, in a placement to an unnamed “Global Institutional Fund Manager” (their capitals). The raising was done at \$1.40 a share, a modest six percent discount.

In September last year, the company also raised \$5.58 million, through a \$4.3 million rights issue and a \$1.28 million placement.

Rhythm shares have moved to a different beat to the rest of the biotech sector, having gained almost 60 percent over the last 12 months.

The shares were at a 12 month (and record) high of \$2.00 in early November 2021 and were as low as 90 cents in mid-August of that year.

The shares were worth a mere four cents in March 2020.

In March, Rhythm was elevated into the ASX All-Ordinaries Index, which consists of the 500 biggest companies on the bourse.

## **Dollars and sense**

The amount Rhythm (or a partner) could charge for the test will depend not just on reimbursement rates, but the forgone expense of not running existing unreliable screening programs.

In the US, the assay likely would be included in an overall annual health check-up.

And compliance with faecal tests in the US is higher (at around 60 percent) because they tend to be part and parcel of preventative screening programs that include free (insurer-funded) colonoscopies.

A blood-based test means fewer false positives and fewer unnecessary follow-up colonoscopies, which are not only expensive but inconvenient and not advisable for many older patients.

Locally, the company has typically used a nominal reimbursement figure of \$50 each, similar to a prostate specific antigen (PSA) test for prostate cancer.

But private insurers are expected to pay considerably more if the blood assays prevent unnecessary colonoscopies, particularly in the US.

The company estimates each FIT test under the National Bowel Screening Program costs the taxpayer \$130 to \$150, all inclusive. That sounds expensive, but not in the context of the \$60,000 to \$100,000 cost of treating each bowel cancer patient.

### **The commercialisation path**

While Rhythm is allowed to sell in Europe, it has not yet done so, pending the signing of one or more partners.

The company's first sales could well derive from other markets, including Asian and Middle Eastern countries that recognise TGA or European approval.

Rhythm could also sell in the US under the 'laboratory-developed test' route, which does not require FDA assent.

Mr Gilbert says Rhythm has been chatting to the "usual suspects" such as the big laboratory equipment suppliers and the big labs themselves.

"There are a lot of lines in the water and some are closer to the boat than others," he says.

One possibility is that the equipment makers supply their instruments to the labs on a 'mate's rate' basis - but with an ongoing commitment to use the kits.

"Equipment makers certainly would be interested in selling the world's only low-cost, mass-market blood test.

"Similarly, you would expect the labs would have a desire to run a test such as this, which doesn't require additional capital equipment and can be included in a routine blood test."

We're kind of guessing, but the test could be of special interest to Sonic Healthcare, which operates the Australian bowel cancer screening program (having won the contract from Healius).

Come to think of it, why doesn't either Sonic or Healius do a deal with Rhythm and then present to government with a combined blood and poo test program?

That way, the health mandarins may well hit their target bowel test compliance rate of 60 percent for the first time.

### **Dr Boreham's diagnosis:**

Colorectal cancer is the second and third most common cancer in women and men, respectively, with 1.9 million new cases and 935,000 deaths annually.

Rhythm estimates the colorectal cancer screening sector is worth potentially \$US38 billion, across an addressable market of 800 million over 50s in US, Europe, China, Japan and Australia.

Of these, 550 million (70 percent) are not tested, currently. If the screening age were to be reduced to age 45, this addressable cohort would expand to one billion people.

In its relatively short-listed life, Rhythm has suffered from premature anticipation on the part of investors, while pandemic-related delays didn't help.

Now, Rhythm is starting to feel like a grown-up company.

"We have done what we told the market we would do," Mr Gilbert says. "We are commercialising this transformative world-leading product that will actually make a difference."

Hip, hip poo-ray to that!

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. After cleaning out the grease trap he finally did the poo test and it's on its way to the lab, courtesy of Australia Poo-st.***