



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: 21 cents; **Shares on issue:** 201,495,811; **Market cap:** \$42.3 million

Chief executive officer: Glenn Gilbert

Board: Otto Buttula (chair), Dr Trevor Lockett, Lou Panaccio, David White, Eduardo Vom

Financials (year to June 30 2020): revenue nil, cash burn \$4.02 million, cash of \$1.79 million*

* Ahead of \$6 million capital raising post balance date

Major shareholders: Otto Buttula 13.6%, Michelle Wing (Ferndale and Northern Star) 9.49%, Loumea Investment 5.93%

A few 'Karens' aside, Australians are largely willing to take the basic steps to avoid the coronavirus - but they are remarkably dismissive about the risks of developing the country's second most prevalent cancer.

Citizens of advancing age would be familiar with the National Bowel Screening Program, which sends out the free Faecal Immunochemical Test - FIT, or the 'poo test' - to 50 to 74-year olds.

Only about 40 percent of recipients bother to execute and return the test, which is yucky to carry out and downright fiddly, while the sample is captured.

Some recipients decline for cultural or personal reasons - and fair enough.

But get this! Of the minority who do send the sample back courtesy of Australia Post, only 68 percent bother to visit their GP for a referral for a colonoscopy (the gold standard detection method).

Not FIT for purpose?

Faecal aversion aside, a key limitation of the FIT test is it only detects blood in the stool, rather than more definitive bowel cancer biomarkers.

Rhythm is working on a blood-based test as a cheaper, more reliable and more palatable alternative to the FIT test.

According to Rhythm chief Glenn Gilbert, 90 percent of bowel cancers are treatable if detected early enough. "It's a 'good' cancer to get if you catch it early because it's an easier fix, versus the alternatives," he says.

Rhythm's Colostat test could be done during a routine doctor check-up for a patient of any age, from the same blood sample used for standard assays such as cholesterol or blood sugar tests. (While the 50 to 74 year olds are most vulnerable, bowel cancer is also the most common cancer for 25 to 29 year olds).

"Some say 'she'll be right, I could just have haemorrhoids or an irritable bowel, so I won't get checked'," Mr Gilbert says.

"But if I'm your doctor and I'm talking to you anyway about cutting down on cheese because you have returned a high cholesterol test, I can say to you 'you might not be dying, but why not get a colonoscopy just in case?'"

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 resources).

Moving to the Rhythm

Colostat is based on intellectual property developed by the venerable Commonwealth Scientific and Industrial Research Organisation (CSIRO), which seems to be behind 99 percent of the nation's technical innovations.

The CSIRO toyed around with the know-how for 13 years before hiving off the tech to Rhythm, which listed on the ASX on December 7, 2017 after raising \$9 million at 20 cents apiece.

In November 2018, CEO and 35-year CSIRO veteran Dr Trevor Lockett was "transitioned" to the role of technical director in favor of Mr Gilbert, then the company's chief operating officer.

Mr Gilbert has a sales and marketing background, having worked in senior roles at Medical Developments and CSL Biotherapies (now Seqirus).

In a further management shuffle, financial services entrepreneur Otto Buttula became chair in November 2019, replacing Shane Tanner.

Mr Buttula then ran a corporate review which saw the company increase staff, especially in the research and development department.

The revamp also saw another shareholder, Eduardo Vom join the board (in June this year).

Mr Vom co-founded the local technology development and commercialization outfit Planet Innovation, which is almost as well known as the CSIRO in biotech circles.

The boring but important bit

While Rhythm still has a way to go, the company is on the cusp of being able to send the test specifications to a third-party contract manufacturer.

For the last few years, Rhythm has been doing the boring but important stuff of identifying the biomarkers and antibodies at the core of the test.

The company has technically validated the final two of five biomarkers that underpin the core intellectual property. This is a key milestone in terms of keeping ahead of putative rivals.

The company initially strived for 10 biomarkers, but Mr Gilbert says management decided it was “inefficient” to strive for such precision when four or five would suffice.

Rhythm has also own won key patent and trade mark approvals and reaffirmed a quality certification called ISO 13485 (nothing to do with ‘iso’ quarantine).

“The development program has come along in leaps and bounds,” Mr Gilbert says. “I’m trying to be calm but we are really excited about how things are progressing.”

Trial, interrupted

Using commercially sourced individual biomarker tests on limited patient samples, the company has shown a superior performance, relative to the FIT samples.

Overall, the earlier studies showed that Colostat had a sensitivity of 73 percent and specificity of 95 percent. Sensitivity is the ability to correctly identify patients with a disease, while specificity is the ability to identify those without the disease.

The FIT tests averaged a 63 percent sensitivity at a 92 percent specificity.

“We would be wanting to better the accuracy of the FIT tests, and we are confident we will achieve that,” Mr Gilbert says.

The company is now in the midst of a full-blown clinical trial, which aims to enrol around 1,000 patients but has been interrupted by the pandemic which caused non-urgent colonoscopies to cease.

The trial will test Colostat’s efficacy relative to a colonoscopy in detecting colorectal cancers and advanced adenomas (benign tumors). The study will also involve “related comparisons” to the FIT tests.

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 has signed up two additional sites: Newcastle’s John Hunter Hospital and the University of Wollongong’s Illawarra Health and Medical Research Institute.

The trial involves 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.

The Victorian poo tests are being collected and the Colostat samples are being safely stored in the freezer.

The route to approval

Mr Gilbert says that “before the world ended” with the pandemic, Rhythm eyed an approval application to the Therapeutic Goods Administration by late 2021.

Now it can’t be definitive on the timeline, which hinged on positive trial results. That said, the company is keen to rev-up recruitment.

Another option is to seek European (CE mark) approval, independently of the trial outcome. “This won’t necessarily mean sales, because you need the clinical adoption, but it will help with further collaborations and partnerships,” Mr Gilbert says.

In the meantime, management is confident the trial will validate the positive vibes from the initial testing.

“We will effectively know the result before we ask the question, based on the cancerous and healthy blood sample testing,” Mr Gilbert says.

As they say in politics: never launch an inquiry unless you know the outcome.

Staying one step ahead of rivals

Rhythm is by no means the only developer of a blood-based cancer test, but Mr Gilbert contends that there is no low-cost blood test for bowel cancer anywhere.

Currently, most non-poo tests are molecular or genetic based - and they're not cheap. Nor are they designed for the mass screening market, such as Rhythm's.

Clinical Genomics (formerly of Sydney and now of New Jersey) has a blood test called Colvera for bowel cancer recurrence, which accounts for 20 to 30 per cent of all cases. Intriguingly, CSIRO helped founder Dr Larry LaPointe to develop that test.

The Belgian based, US-listed Volition Rx is developing Nu Q, a blood test for bowel and lung cancers. But as well as being a more complex molecular test, it is also dearer.

Finances and performance

Rhythm's revenue proposition is based on both undercutting the cost of the existing tests and reducing the incidence of bowel cancer hospitalizations through more effective screening to the global mass market.

The company estimates a FIT test could cost the National Bowel Screening Program \$130 to \$150 each, while bowel cancer can cost the health system \$60,000 to \$100,000 per patient.

The Colostat test is expected to be reimbursed for approximately \$30 to \$50 each. This is similar to the prostate specific antigen (PSA) test, despite having four more biomarkers.

With first revenue not expected until sometime in late 2022 or early 2023, Rhythm has replenished its coffers with a \$6 million raising, via a \$2.4 million placement and \$3.6 million three-for five rights issue.

Mr Buttula kindly chipped in \$1.5 million of the placement which, as with the rights issue, was struck at six cents a share.

The company also banked a \$1.1 million research and development tax incentive.

So far this calendar year Rhythm shares have plumbed a record low of four cents (March 27) and a high of 31 cents (October 6) - not far off the zenith of 36.5 cents on the December 27, 2017 listing date.

Mr Gilbert says he was getting plenty of "unofficial advice" - a.k.a. abuse - from shareholders when shares wallowed.

"Now they are all ringing and saying they want more shares," he says.

Indeed - winners are grinners.

Dr Boreham's diagnosis:

It doesn't take a Nobel Prize winner in medicine to appreciate the benefit of an easy and widely available blood-based test for bowel cancer.

The company estimates the colorectal cancer screening sector is worth potentially \$38 billion, across key target geographies of US, Europe, China, Japan and Australia.

Of the 769 million 50 to 74 year olds in these countries, circa 530 million (69 percent) remain unscreened.

Mr Gilbert says Rhythm's mass market test is on-trend, in that blood-based tests are now standard for detecting cervical cancer (an evolution from the 'scrape' test) and prostate cancer.

If approved and commercialized, Colostat should appeal to governments by increasing screening coverage at a lower cost. And if the incidence of bowel cancer is reduced, private health insurers might be willing to adopt Colostat and fully fund colonoscopies (as is the case in the US).

According to Mr Gilbert, some investors believe the company has been "over enthusiastic" about the timeline to commercial development.

That's a common problem. But as with one's favorite sports team, we would rather an excess of zeal and ambition than a dearth of one.

"Whether it's this year, next year or the year after, this is a massive opportunity for a small Australian company to take over the world," Mr Gilbert says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. What he lacks in formal qualifications he makes up for in over enthusiasm, but will settle for domination of Goat Island* rather than the world.

[* Editor's note: it's in Sydney Harbour – google it]