



ColoSTAT comeback, with Genetype upside

Rhythm Biosciences (ASX:RHY) is a cancer diagnostics company. Since its listing, the Company has been focused on ColoSTAT, a blood test for colorectal cancer. While ColoSTAT is still a focus of Rhythm Biosciences, and the Company is in the early commercialisation phase, the late-2024 acquisition of Genetype could change investor perception entirely.

GeneType offers further upside (and potentially earlier)

Rhythm Biosciences ceased to be a 'one trick pony' when it acquired Genetype. GeneType is an AI-driven test to help people know and manage their cancer risk by determining a risk profile and a personalised health management path. This may include recommending ColoSTAT where appropriate. The irony is that The Genetype business has provided revenue to Rhythm Biosciences before ColoSTAT and will serve as both a lucrative business in its own right as well as a 'funnel' for patients that may need ColoSTAT. Rhythm Biosciences' total product suite could be appropriate for ~0.5bn individuals worldwide by enabling earlier and thus more effective forms of treatment.

ColoSTAT is 'go' in Australia, second time lucky

Rhythm Biosciences is in a far better position with ColoSTAT than it was this time two years ago. 2023 had been defined by its inability to get TGA approval, not because of any lack of efficacy, but because more independent production batches were needed than the Company possessed at that time. But Rhythm Biosciences has just entered the market, offering the test through its Melbourne lab as a clinical laboratory service which clinicians can order on their clinical judgement. The Company plans to broaden its market further in 2026, specifically once it receives NATA variation to scope assessment and this would support broader clinician use. As long-term followers of Rhythm Biosciences would know, ColoSTAT has higher sensitivity and is far less awkward, costly and time-consuming than the government-funded Faecal Immunochemical Test (FIT) used as part of the national bowel cancer screening program.

Valuation range of A\$0.45-0.69 per share

We value Rhythm Biosciences at \$0.45 per share in a base case scenario and \$0.69 per share in an optimistic (or bull) case scenario, using a DCF methodology, valuing the Company as a unified group rather than a sum of its parts. With CY26 set to be a year of significant growth for both GeneType and ColoSTAT, investors may not have long to wait to realise upside in the stock. Please see page 19 for further details on our valuation and page 22 for the key risks associated with our thesis.

Share Price: A\$0.205

ASX: RHY

Sector: Healthcare and Life Sciences

17 February 2026

Market cap. (A\$ m)	69.5
# shares outstanding (m)	338.6
# shares fully diluted (m)	446.0
Market cap ful. dil. (A\$ m)	91.8
Free float	100%
52-week high/low (A\$)	0.255 / 0.051
Avg. 12M daily volume ('1000)	555.8
Website	https://rhythmbio.com

Source: Company, Pitt Street Research

Share price (A\$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A\$ per share)	0.45-0.69
WACC	14%
Assumed terminal growth rate	2%

Source: Pitt Street Research

Disclosure: Pitt Street Research directors own shares in Rhythm Biosciences.

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The Investment Case for Rhythm Biosciences

- 1) **Rhythm Biosciences is in better shape than it has ever been.** The Company has now commercialised ColoSTAT and has reduced the risk of being exposed to a single product by bringing GeneType into its fold. GeneType is essentially a suite of personalised predictive tests that predict risk of a range of chronic disease development (currently only 6 kinds of cancer but this is expected to expand over time). And ColoSTAT is a simple blood test for colorectal cancer.
- 2) **The Company's product suite has strong potential to make a difference in cancer risk detection and screening.** Both GeneType and ColoSTAT can help detect cancer earlier (through earlier screening) and this can lead to earlier intervention and more effective treatment options. Compared to existing options on the market, these options are lower-cost, have higher sensitivity and efficacy, plus ColoSTAT comes with the advantage of being more convenient and less invasive (at least compared to the government-funded Faecal Immunochemical Test).
- 3) **Both GeneType and ColoSTAT are based on several years of R&D work that have validated it.** GeneType has originated from over 20 years of R&D work and earlier generations of tests. ColoSTAT originated out of roughly a decade's work at the CSIRO that began in the mid-2000s, and Rhythm Biosciences has built on this since its 2017 listing by simplifying the number of and settling on antibodies applicable to the test and finding impressive levels of sensitivity and specificity. The most recent study depicted 81% sensitivity and 91% specificity.
- 4) **There are enormous market opportunities awaiting the Company with both GeneType and ColoSTAT.** The Company believes there is a market of over 500 million people globally for GeneType. As for ColoSTAT, if it could serve as part of routine screening, there is a market of millions of people. We have estimated there are 7.4 million people in Australia between 50 and 74 (the age where the colorectal cancer screening program occurs) and there are 96.7m in the US and 20.8m in the UK. In both instances, even if Rhythm only penetrates a small proportion of the market, there is still a significant opportunity.
- 5) **GeneType is already revenue-generating and there is potential for growth ahead.** Rhythm Biosciences made its first commercial sales from GeneType within weeks of the acquisition from patient cases picked up under GTG's ownership. Although the revenue in CY25 was immaterial, this is expected to increase over time as it reaps the benefits of the building blocks established since the purchase including NATA accreditation for laboratory operations and the initial strategic partnership pilot that began in late FY25.
- 6) **2026 will be the year ColoSTAT begins to reach its commercial promise.** The Company is already offering ColoSTAT through an ISO 15189-accredited laboratory in Melbourne (through a framework similar to the CLIA path in America) that Rhythm Biosciences picked up in conjunction with the GTG acquisition following that company's administration. From 2026, Rhythm will offer ColoSTAT as a diagnostic alternative for symptomatic individuals where stool-based testing will be unsuitable, unavailable or not preferred.
- 7) **Several major catalysts await in 2026.** Beyond commercial revenues for GeneType and ColoSTAT, other catalysts could help create shareholder value in the short-term and lay the foundations for larger-scale growth in the longer-term. In respect of ColoSTAT, Rhythm is currently completing



NATA accreditation and plans to resubmit to the TGA utilising its data and experience since the withdrawal of its first submission in 2023. Rhythm is also working on a lung cancer screening assay and anticipates completing pre-clinical data evaluation and the design of an assay prototype in CY26.

- 8) **Rhythm has the right leadership team.** While Rhythm has seen some turnover since its listing at a board and management level, we think it now has the right team in place that possesses significant experience in commercialising diagnostic innovations. The Company has hired experienced company director Gavin Fox-Smith as Chair following the retirement of Otto Buttula at last year's AGM. The acquisition of GeneType led to GTG's Scientific and Medical Advisory Board joining forces with Rhythm and supporting both GeneType and ColoSTAT.
- 9) **We believe Rhythm is undervalued** at its current market value. We value Rhythm at \$0.45 per share in a base case scenario and \$0.69 per share in an optimistic (or bull) case scenario. These represent market capitalisations of \$153.2m and \$234.7m and are significant premiums to the current market capitalisation of \$40m. We think if the Company reaches its commercial objectives in 2026, this can go a long way towards realising its value.



Rhythm Biosciences is now more than just ColoSTAT

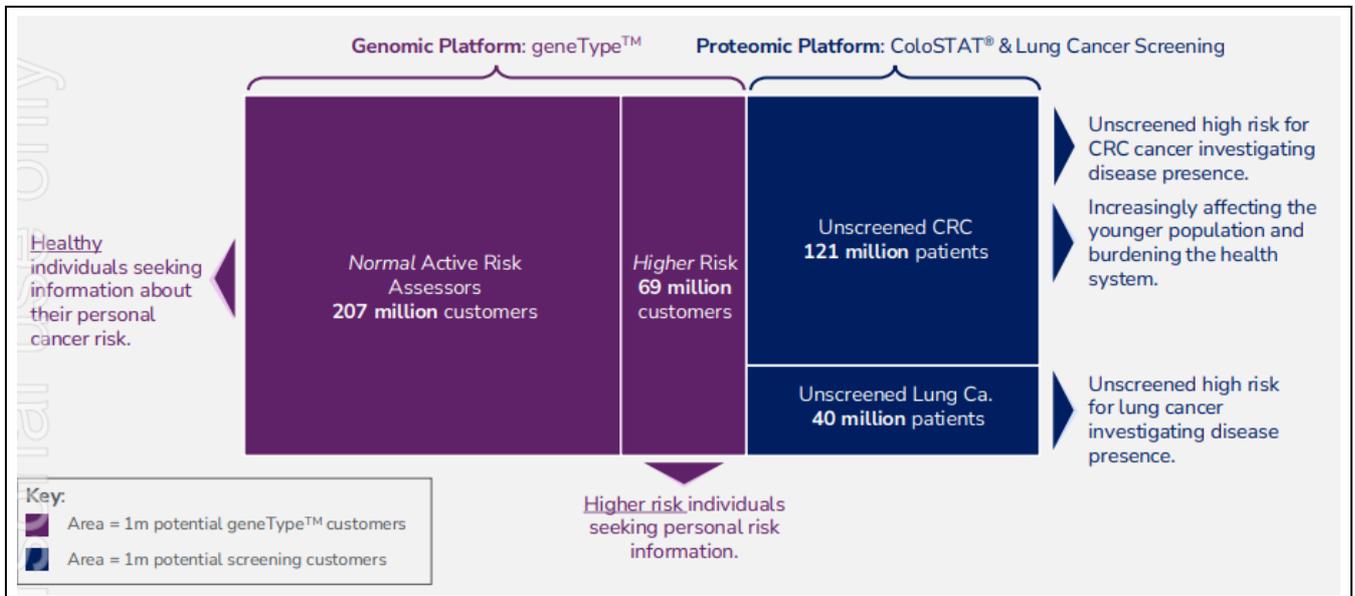
Rhythm Biosciences was focused solely on ColoSTAT until 2024 when it bought Genetic Technologies' IP that bought the Genetype business into its fold.

Since its 2017 IPO, Rhythm Biosciences has been focused on the commercialisation of ColoSTAT. ColoSTAT is still a focus of the Company although GeneType is also a focus. In fact, it is more important because it has a larger market opportunity and is already commercialised, even if one could argue investors are not placing any value on it at all. We hope our report can help investors understand the opportunity better.

The Genetype business came into Rhythm Biosciences' fold thanks to the 2024 administration of previous owner Genetic Technologies. The acquisition cost a little over \$600k, was completed ahead of schedule, and comprised of licenses, customer contracts and test infrastructure. The first sales, a legacy of former ownership, were recorded in early 2025. The Company's opportunity is to take GeneType to the next level, now that the hard work of developing the technology and taking it to the point of first sales has been done.

We will delve into the GeneType technology more comprehensively in the next section of this report. For the purposes of this section, we note that GeneType is complementary to ColoSTAT in enabling earlier diagnosis of cancer. Where GeneType differs is it will enable patients to determine their risk profile. In the specific case of colorectal cancer, GeneType could also help in decide people who need to use ColoSTAT. In both cases, in people knowing they are at risk, getting tested and being identified earlier enables earlier disease detection and improved outcomes. It also enables a far larger market – indeed a nearly quadrupled one from 121m unscreened colorectal patients to ~0.5bn (Figure 1).

Figure 1: Rhythm's markets



Source: Company



GeneType – Pioneering cancer risk testing

Rhythm Biosciences picked up GeneType in late 2024 after its original owner Genetic Technologies went into administration. The deal included the IP, existing contracts, patient data, personnel and commercial infrastructure. GeneType provides predictive risk scores that help healthcare practitioners assess susceptibility to cancer and other diseases — a complementary capability to Rhythm Biosciences’ blood-based diagnostics.

What is GeneType and how does it work?

The test, which is conducted using a simple cheek swab, is based on several risk factors including polygenic risk, parity, BMI, lipid levels, breast density, blood pressure and cholesterol levels (Figure 2). There are individual tests for each of these factors individually, but GeneType combines all of these to conceive a percentage chance of developing particular diseases and this is called a Polygenic Risk Score (PRS) (Figure 3). Currently, Rhythm Biosciences is focused on 6 kinds of cancer: Breast, Prostate, Colorectal, Ovarian, Melanoma and Pancreatic. GeneType is expected to expand to other indications (cancer and non-cancerous) over time.

GeneType is based on several risk factors, combining them to conceive a percentage chance of developing particular diseases.

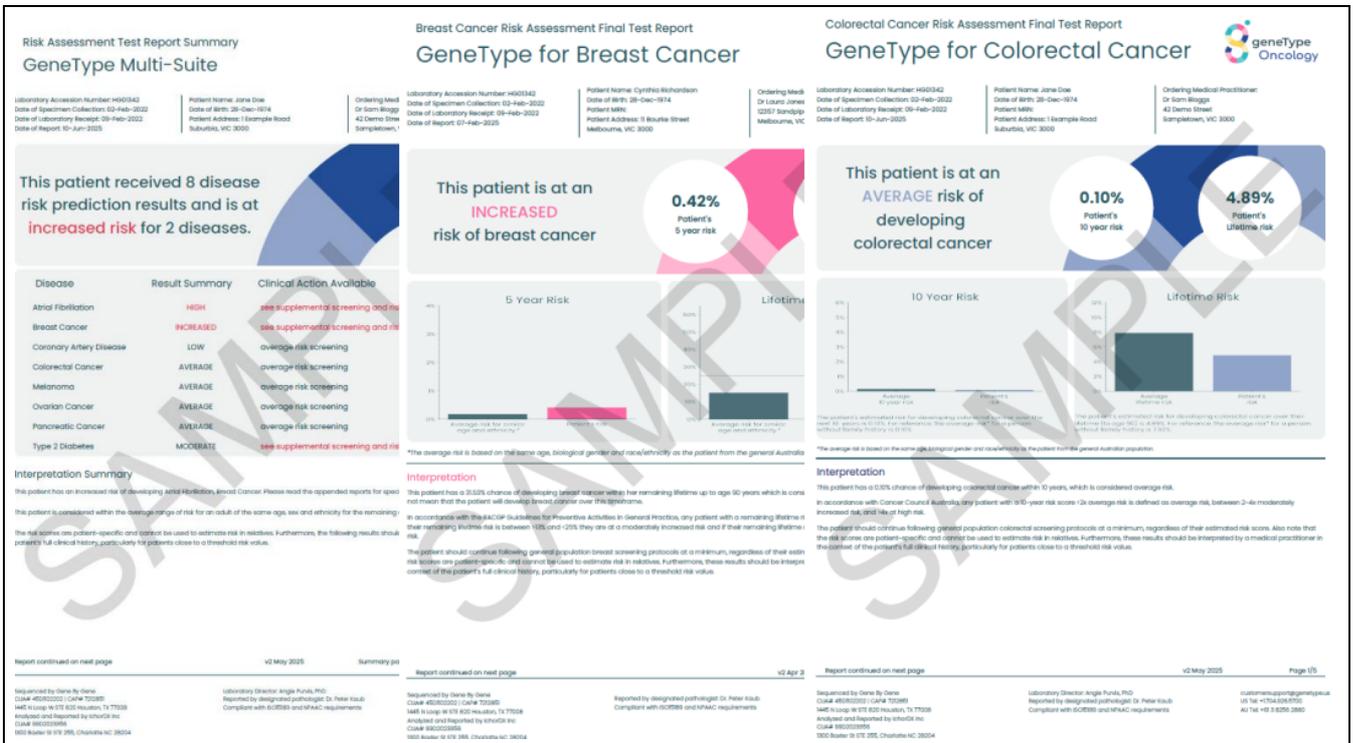
Figure 2: GeneType Collection Kit



Source: Company



Figure 3: Sample GeneType reports



Source: Company

GeneType's mechanism has been validated in at least two major studies.

How can the risk of developing diseases be detected in this way? Diseases such as cancer can be typified by continuous change in cellular DNA, RNA (genome) and proteins (proteome). Disease risk prediction using genomic information predates the disease by several years (i.e. <10). Now this is not the same as a formal diagnosis of the disease, but identifying the risk early could enable lifestyle changes and/or other interventions which may delay or even prevent disease from occurring. In doing so, this prevents societal burdens that come with the diseases.

Does this actually work? Yes, GeneType's mechanism has been validated in at least two major studies. The first was the so-called UK Biobank Study. Completed in 2021, it investigated how well a polygenic risk score comprised of 45 SNPs stratifies risk of colorectal cancer when applied to the UK Biobank cohort and compared this in its own right as well as in combination with first-degree family history of colorectal cancer. The study found that the combined model could identify people without a family history who had genetic risk equivalent to someone who did have an affected first-degree relative. Moreover, including the PRS with family history produced a broader risk distribution than family history alone and improved discrimination of lifetime risk and 10-year risk¹.

The second was completed in December 2025, focusing on ovarian cancer and using data from the Nurses' Health Study, a long-running cohort (one of the world's longest-running, not to mention the largest) that began in 1976 and includes more than 275,000 participants. Like the Biobank Study, the aim was to evaluate how well an integrated risk prediction model (combining clinical

¹ Gafni A, Dite GS, Spaeth Tuff E, Allman R, Hopper JL. (2021) Ability of known colorectal cancer susceptibility SNPs to predict colorectal cancer risk: A cohort study within the UK Biobank. PLoS ONE. 2021;16(9):e0251469. doi:10.1371/journal.pone.0251469.



risk factors, family history and a PRS) stratifies risk, although it focused on ovarian cancer. The study confirmed that such a combination more effectively identifies two times more women at elevated ovarian cancer risk than using clinical or genetic information alone².

GeneType originated from a late 1980s hypothesis that non-coding DNA regions had useful information that could indicate diseases.

History of GeneType and its development

GeneType traces its development history back to Switzerland in the late 1980s. The original company that bore the technology's name was formed to test the hypothesis that non-coding DNA regions (particularly the non-coding DNA of the human HLA gene complex on chromosome 6) was a valuable and highly ordered reservoir of useful genetic information³.

It was already common knowledge that even very slight variations in genetic sequence can drastically change how a gene functions and cause variations and so genetic testing could be useful. Sometimes differences in the human body caused by such variations could be minor like a different eye colour than would otherwise be the case, or sometimes more major changes such as how individuals respond to drug therapies, or it can even indicate the risk of diseases such as cancer, cystic fibrosis or cardiovascular disease. But the radical idea by the Company's founders was that information from non-coding DNA regions was not 'junk'⁴ but could be just as useful as other regions. From this original work, the Company known as Genetic Technologies was formed in 2000 to acquire the IP that had been developed by that time.

Over time, GTG launched genetic risk tests including BREVAGen in the early 2010s which was the first commercially available test of its kind focused on combining numerous small effect genetic variants rather than single mutations. The GeneType moniker was introduced in 2019.

In February 2022, GTG launched GeneType Multi-Risk Test which assesses risk across multiple common serious diseases including various types of cancer as well as Type 2 diabetes and coronary artery disease. It used a PRS framework which adds together many genetic variants each with small effect sizes, plus clinical risk factors, to estimate personalised long-term risk. In other words, it could detect the risk of several diseases, using the same genetic and clinical algorithms as opposed to using one end point.

GeneType is better than alternatives, including BRCA

Rhythm Biosciences considers the main competing test to be BRCA tests which are named after the namesake hereditary cancer genes. Inherited mutations in BRCA genes (BRCA 1 and BRCA 2) significantly increase the lifetime risk of breast and ovarian cancers. The Company believes that GeneType is superior because it assesses more risk factors (particularly many common low penetrance genetic variance) and could therefore be applicable to up to 20% of the population. BRCA tests only cover their own genes and not the fully polygenic background of risks whilst GeneType estimates the accumulated effect of *many* common variants across the genome to show risk likelihood. We do not have space to outline all the different alternative tests, but they would have similar shortcomings in assessing less risk factors.

² ASX announcement 1 December 2025.

³ Genetic Technologies Annual Report 2004, p.16.

⁴ The term 'junk' is not our own colloquial language, but this was a specific term used for non-coding regions. This term has fallen out of favour in the scientific community but is still used because these regions are non-coding even though we now know useful information can be obtained.



Who could use GeneType?

The market could include both patients that are known to be at higher risk (and would be recommended on the initiative of their GP), but also lower risk individuals taking proactive steps to monitor their health (Figure 4). As shown in Figure 1, Rhythm Biosciences believes there are 69m potential customers in the former category and 207m in the latter⁵. Even a small market penetration would derive a large number of customers – a mere 1% market penetration would represent 2.76m patients. And this does not include unscreened patients for colorectal and lung cancer which are 121m and 40m respectively, and these patients could be suitable for ColoSTAT and Rhythm Bioscience’s lung cancer screening mechanism respectively.

Figure 4: The market opportunity

	1 Worried well – Proactive Preventers	2 Active Risk Assessors – Actively engaged in assessment	3 At Higher Risk – Seeking more information
Summary	A desire to understand their risks.	Encounter a reason to believe their risk is higher than average – typically age.	Urgency in need to assess risk. Available information unsatisfactory.
Use case	Otherwise, <u>healthy</u> but intervene to ensure longer healthspan.	Are engaged in population screening initiatives due to age, family or clinical history.	Possibly symptomatic or considered high risk. Reflex test for negative mutation testing or negative biopsy.
Sales channel	Corporate programs, primary carers, functional clinics, General Practice.	General Practice, Clinical geneticists, Specialists, Corporate programs.	Clinical geneticists, Specialists

Source: Company

In 2025, Rhythm Biosciences entered into several key distribution partnerships for geneType.

The Company’s commercial plans with Genetype

2025 was a year of modest revenues from legacy commercial arrangements with previous owners, but Rhythm Biosciences entered into several key distribution partnerships that will take revenues to the next level. The Company has promised significant quarter on quarter revenue growth milestones (over 100% in Q1 of FY26) and its sales pipeline is growing rapidly.

The first partnership of note was a strategic pilot with a leading Australia pathology provider. The second is a strategic agreement with Memorial Sloan Kettering Cancer Centre, providing GeneType services supporting studies focused on breast and prostate cancer risk. The third made GeneType available on the Know Your Lemons mobile application, run by the namesake American non-profit organisation dedicated to breast cancer education and early detection and has a global reach of more than 2 billion people online as well as education programs delivered in-person in over 75 countries. The fourth was with Catch Bio, which is a cancer prevention platform that enables individuals to identify, analyse and actively manage their cancer risk. GeneType will enhance Catch Bio’s platform by providing clinically validated polygenic risk assessment across up to 6 cancers.

For now, GeneType's greatest potential is in cancer. But down the track, it could help with diabetes, specifically Type 2 diabetes. Diabetes involves insufficient insulin production from pancreatic beta cells, frequently with cellular insulin resistance. A pre-diabetic state or diagnosis of type 2 diabetes increases risk of developing macro-vascular comorbidities, primarily

⁵ Rhythm Biosciences October 2025 investor presentation, slide 17. The slide notes that references are available on request.



cardiovascular disease, cancer and psychiatric disorders. There have been greater efforts to proactively screen individuals for risk and there are various clinical risk scores such as the Framingham Offspring Study.

Studies conducted by Genetic Technologies show that adding its PRS to the Framingham type 2 diabetes risk prediction score statistically significantly improved the ability to distinguish between affected and unaffected people compared to the Framingham model alone. It can effectively stratify the population from low risk to very high risk and people in the top 20% of risk are 25-times more likely than the bottom 20%⁶.

Our conclusion on Genetype

Given that the Company's market capitalisation barely moved for several months post-completion of the deal, it would be fair to assert the market is placing little to no value at all on GeneType. In fairness to investors, it can take a while for their thinking on companies to shift when a company has been exclusively focused on one product for as long as Rhythm Biosciences had been focused on ColoSTAT. And arguably, a biotech asset acquired out of Administration for \$600,000 may not necessarily stand out as one with potential to change the course of a company forever. There are companies with drugs at a pre-clinical stage that are higher valued than the price GeneType was bought for.

But GeneType should change investor thinking on Rhythm Biosciences altogether. Above everything else, GeneType has significantly expanded Rhythm's market and potential revenue. Yet it has generated revenue even before ColoSTAT and help people who want to proactively monitor their health as opposed to those merely at high-risk. Moreover, it could also serve as a 'funnel' for ColoSTAT users.

Although we ultimately chose to value Rhythm Biosciences as a combined company selling both ColoSTAT and GeneType, preliminary stage modelling depicted the Company as far more valuable with both assets than if it just had ColoSTAT. We think that if established partnerships can convert into revenues, that will be the time investors (both those already invested in Rhythm Biosciences and those considering an investment) will pay more attention to GeneType and its potential.

GeneType should change investor thinking on Rhythm Biosciences altogether.

⁶ Genetic Technologies submission to Australian Parliamentary Inquiry Into Diabetes. 20 September 2023.



ColoSTAT

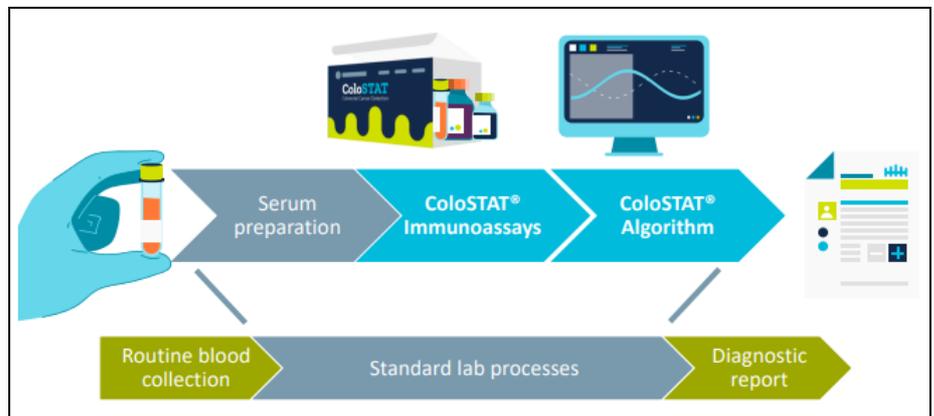
What is ColoSTAT and how does it work?

ColoSTAT is a blood test that is based on the detection of certain proteins that vary in concentration in the blood of patients with and without colorectal cancer.

ColoSTAT is a blood test that is based on the detection of certain proteins that vary in concentration in the blood of patients with and without colorectal cancer. Proteins are routinely produced from the cells in our body and get released into the blood. The levels of proteins being produced and released into the blood can be affected by the type and health of our cells.

After a patient draws blood, ColoSTAT would use antibodies for the lead biomarker to measure proteins levels in the patient's blood. The concentrations of these proteins would then be weighted using an algorithm, which in turn generates a colorectal cancer risk score that gets inputted into a diagnostic report readily for the GP to discuss with the patient (Figure 5).

Figure 5: How ColoSTAT works



Source: Company

Where ColoSTAT all began and how it developed

ColoSTAT began from work at the CSIRO from which Rhythm Biosciences acquired the IP and bought it to commercialisation.

Rhythm Biosciences picked up ColoSTAT in 2017 just prior to its IPO. Prior to that, the CSIRO had undertaken the work that would lead to ColoSTAT since 2003 in identifying 68 proteins that change in patients with and without colorectal cancer, then finding the 10 most likely to show up. The Company used this work to develop this work into a test kit, and a viable one at that. Further studies (Studies 6 and 7) were undertaken to further validate the technology and simplified the biomarkers down to 5.

The most recent study depicted 81% sensitivity and 91% specificity, not to mention a 99% Negative Predictive Value⁷ (Figure 6). Moreover, ColoSTAT has been shown to be consistent across all stages of colorectal cancer as well as in patients of both genders and a wide range of ages⁸ - the latter a critical point with the increasing frequency of new cases of bowel cancer in those <50 years of age. Now, in early 2026, Rhythm Biosciences is in the early stage of commercialisation with ColoSTAT.

⁷ The probability that a person with a negative result will not have the disease.

⁸ Between the ages of 28 and 91 as per ASX Announcement 30 October 2025.



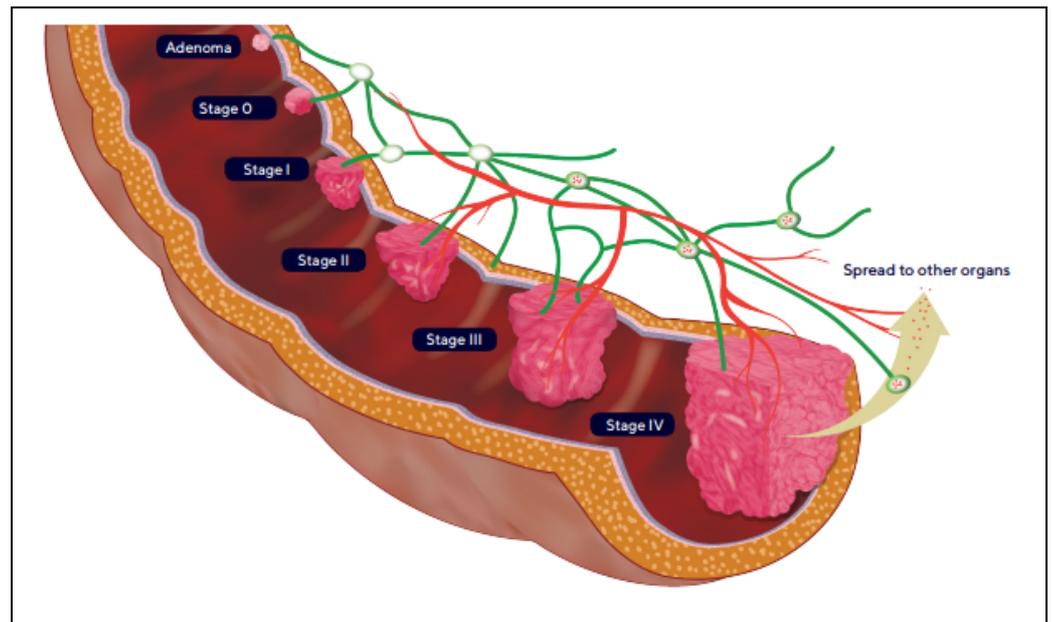
Colorectal cancer, also known as bowel cancer, is one of the most common type of cancers

The hope of ColoSTAT: To ease the burden of colorectal cancer

Colorectal cancer, also known as bowel cancer, is one of the most common type of cancers. It was estimated that there were 1.9m cases in 2022 and 900,000 deaths⁹. Moreover, these figures could rise to 3.2m cases and 1.6m deaths annually by 2040 if current trends continue. Many of the risk factors relevant to other cancers are applicable including ageing populations, metabolic risk factors like obesity, and lower physical activity.

This is despite screening programs in some places such as Australia, which we will cover shortly. We also would observe that while some cancers like skin and breast cancer may be detectable by physical signs such as lumps in the skin, this isn't the case with colorectal cancer at least at early stages as the colon is inside the body and visible external symptoms such as blood in the stool may not occur until the cancer is at a later stage when treatment may be difficult (if at all possible) (as per Figure 6 and Figure 7). Yet, if cancer is detected earlier, interventions can be taken which are more likely to succeed. And this is what ColoSTAT can do, and better than the status quo.

Figure 6: The stages of colorectal cancer and their visibility



Source: Company

⁹ Wu, S. et al. 2025 'Global burden of colorectal cancer in 2022 and projections to 2050: incidence and mortality estimates from GLOBOCAN', *BMC Cancer* 25, 1770. <https://doi.org/10.1186/s12885-025-15138-0>



Figure 7: Overview of the stages of colorectal cancer

Stage	0	I	II	III	IV
Description 	Abnormal cells are found in the epithelium (mucosal layer) lining the bowel wall, most often outgrowths (adenomas or polyps). These abnormal cells may become cancer and spread.	Tumour has invaded beyond the epithelium of bowel into the muscle layers below but has not spread past the bowel wall.	Cancer has grown through the muscle layer of the bowel and invaded nearby tissue, but has not spread to the lymph nodes	Cancer has spread to the nearby lymph nodes but not to other parts of the body	Metastatic bowel cancer where it has spread beyond the colon and rectum to other organs such as the liver or lung.
5-year % survival rate	>96%	93%	82%	59%	8%
Treatment  	Typically, surgery to remove the adenoma or local excision through a colonoscope. Removing part of the colon (partial colectomy) is occasionally needed if a tumour is larger.	Cancers of this stage require removal of the affected section of the large bowel but typically no additional treatment is necessary.	Partial colectomy along with dissection of nearby lymph nodes may be the only treatment needed. Adjuvant chemotherapy may also be required.	Partial colectomy along with dissection of nearby lymph nodes, along with adjuvant chemotherapy. Radiation therapy and/or chemo may be options for people not healthy enough for surgery.	Neoadjuvant chemotherapy to reduce tumour size followed by surgery. Additional therapies also needed as well as radiation therapy and still only an 8% chance of survival.
					

Source: Company

ColoSTAT is intended to replace the FIT (Faecal Immunochemical Test).

What ColoSTAT is superior to: the FIT

The hope is that ColoSTAT can be superior the FIT (Faecal Immunochemical Test). The FIT is routinely mailed out every 2 years to all Australians aged 50-74 as this is the age where the risk is higher notwithstanding the incidence is on the rise in younger populations.

With the FIT, the patient takes a sample of his or her stool, places it in a special collection tube or on a special card and sends it to the lab for testing. An antibody that binds to a blood protein called haemoglobin is used to detect any blood. In fairness, the test and the program more broadly:

- Aligns with national and international best-practice guidelines in screening every two years,
- Was developed from large international trials depicting that faecal blood can be a sign of bowel cancer,
- Was an improvement from the earlier generation FOBTs (Faecal Occult Blood Tests) which were even less sensitive, but even then, needed multiple samples that could be impacted (both in the sense of failing to detect cancer but even generating false positives as blood can occur from other causes like haemorrhoids) by people's diets.

However, there are four key problems with the test.

- **It is a triage test**, rather than a diagnostic one for cancer. All it does is recommend people for colonoscopies. Colonoscopies may detect cancer but may not be definitive, come with their own risks and in any event would overburden the health system even if just the people who did the FIT underwent them (let alone those who ignore the FIT did too).



The drawbacks of the FIT mean participation rates are 40-45%, but a 60% rate would see bowel cancer deaths drop dramatically.

- **It only searches for blood in the stool** which may not always be cancer and even then, may only occur at later stages,
- **It is still very cumbersome.** The stool needs to be collected on clean toilet paper and must not come into contact with water or urine. And then the sampling probe from the test kit has to be poked into six different areas of the stool sample! And that's before having to properly seal and pack the test kit and fill out the relevant forms before the kit is mailed back.
- **There is a 'yuck factor' given the above,** even before considering the cumbersome process.

All these mean that it is not highly taken up – participation rates are 40-45%. Modelling has shown that even if participation rose to 60%, bowel cancer deaths would drop dramatically¹⁰. But realistically, a better way of testing is far more likely to hike participation, and this is what ColoSTAT offers.

Why ColoSTAT is better

ColoSTAT in contrast has 5 key benefits (Figure 8):

- A simpler and less nauseating process,
- Is likely to be lower cost. Australia costs ~A\$200 but certain competitor tests in America can cost up to US\$949¹¹,
- More likely to be preferred. Indeed, at least one survey has suggested that blood tests are the preferred screening method in over 83% of the currently unscreened population¹² and other studies have shown even higher figures¹³¹⁴,
- Can operate at scale. It is all well and good for a company to be able to develop one single assay kit that works, but it needs to be scalable while being able to be made fast and not compromise on quality. Testing on the latest generation of kits (the Beta kits) was completed in May 2025,
- Has a superior test performance (Figure 9).

ColoSTAT can help detecting cancers earlier as well as avoid unnecessary colonoscopies. It is unlikely to replace the government funded FIT altogether (at least under RHY's current commercialisation model) but still fulfil an important role in bowel cancer screening. Doctors could use both tests to identify patients who could be prioritised for colonoscopies as well as rule out those who have no need for them at all (if you are negative, there's a 99% chance you do not have it).

For instance, doctors may see patients with symptoms consistent with bowel cancer, or an FIT result could raise concerns. A 'positive' FIT combined with a positive ColoSTAT result would indicate a patient should have a colonoscopy whereas just the first may not be conclusive because it just monitors blood in the stool and this can happen for reasons other than cancer (i.e. mere haemorrhoids or inflammation). Keep in mind too that the FIT is only mailed every two years so ColoSTAT could be recommended if a doctor thinks their patient should be tested immediately, or of course if the FIT is unappealing in the first place.

¹⁰ Lew, J. 2017, Long-term evaluation of benefits, harms and cost-effectiveness of the National Bowel Cancer Screening Program in Australia: a modelling study, *Lancet Public Health*; 2(7), pp.331-340. <https://pubmed.ncbi.nlm.nih.gov/29253458/>

¹¹ Investor Presentation June 2023, slide 12

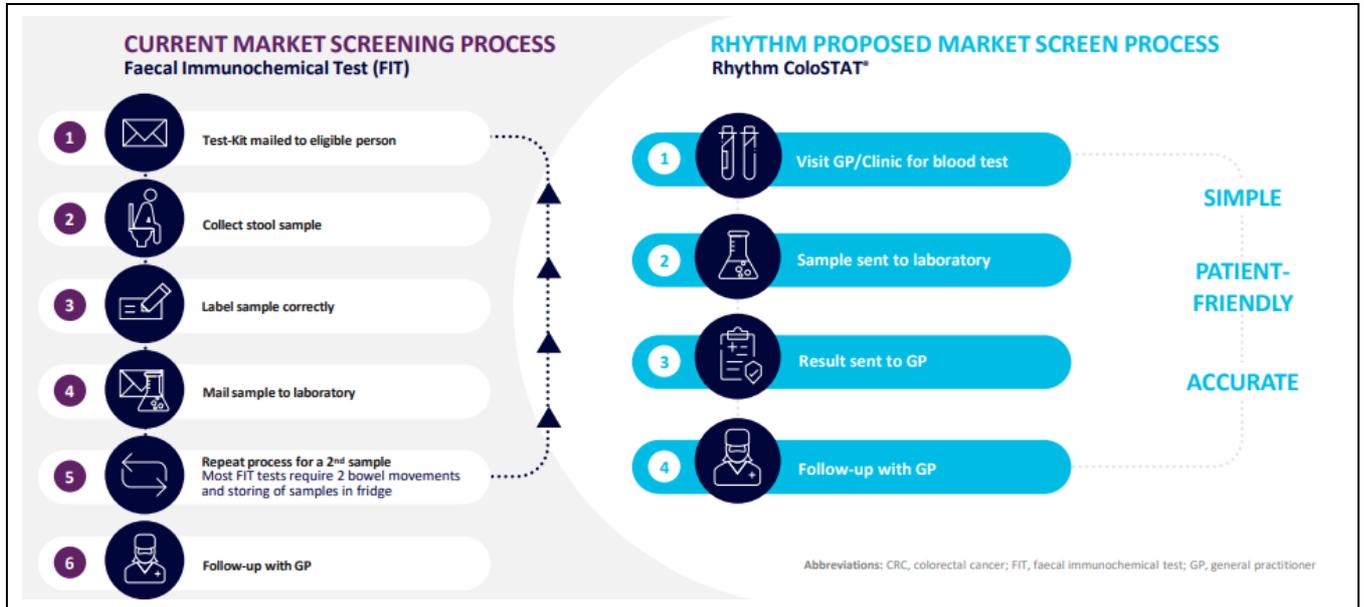
¹² Osborne et. al. 2012, Sample preference for colorectal cancer screening tests: blood or stool? *Open Journal of Preventive Medicine*, 2012; 2(3):326-331.

¹³ Ioannou S, Sutherland K, Sussman DA, Deshpande AR, 2021. Increasing uptake of colon cancer screening in a medically underserved population with the addition of blood-based testing. *BMC Cancer*. 2021;21(1):966. doi:10.1186/s12885-021-08678-8

¹⁴ The study mentioned in Ioannou showed an increase in uptake from 12.6% to 93.5% when the offering switched from the FIT to a same-day blood test.

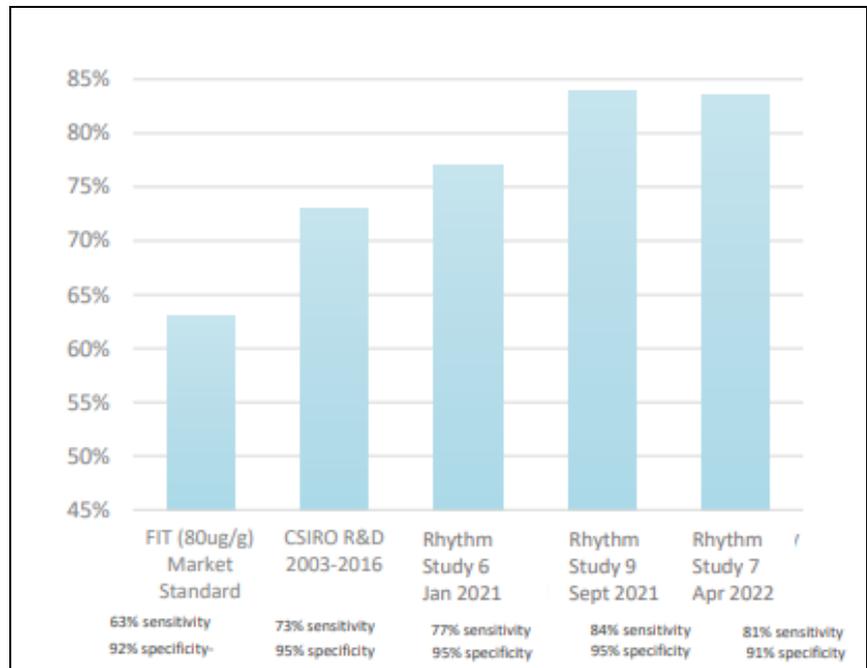


Figure 8: FIT vs ColoSTAT



Source: Company

Figure 9: FIT vs ColoSTAT



Source: Company



Rhythm's commercial plan and regulatory pathway for ColoSTAT

In Australia, the Company sought TGA approval via the conventional pathway but has been unsuccessful, having made an application in 2023 and withdrawing it following regulatory feedback. There was no problem with ColoSTAT's efficacy, but more independent production batches were needed than the Company possessed at that time.

Rhythm Biosciences now has these, but in order to get ColoSTAT to market faster, the Company is following a different pathway – still an approval process, but a different pathway to its previous attempt. Some investors may view conventional TGA/FDA approval as the only way to the market and/or think the process with test kits is the exactly the same as for drugs or medical devices. *Neither* of those conceptions are true. Let's look at where Rhythm Biosciences is already at, and where it is aiming to head to in the next couple of months.

- **Step One (where Rhythm Biosciences is now):** Since December 2025, the Company has sold through its own laboratory initially to selected clinical leaders who choose ColoSTAT under their own judgement. ColoSTAT is being provided not as a product but as a clinical laboratory service offered by an ISO-accredited lab (RHY's lab has ISO15189:2022 Accreditation). The risks and control are being managed by the lab's quality system, and these quality systems are approved. Currently Rhythm offers ColoSTAT for use in individuals with symptoms consistent with colorectal cancer, particularly where stool-based testing is unsuitable or not preferred.
- **Step Two (where Rhythm Biosciences is aiming for):** Rhythm has been progressing a variation-to-scope assessment with NATA to formally put ColoSTAT within its accredited laboratory services. In other words, it will no longer be just a general lab service but a lab service with ColoSTAT. This would support broader clinician use and commercial rollout beyond initial limited programs and strengthen clinical confidence with formal accreditation.

The accredited labs pathway is essentially the same CLIA pathway that Lumos Diagnostics (ASX: LDX) has pursued for American commercialisation in that tests can be sold through accredited labs. The blood samples will be sent to Rhythm's laboratory directly and the results will be sent back to the patient's referring GP. ColoSTAT will not (yet) be a stand-alone product sold externally – it is only used within the accredited lab, handled by trained professionals only in that lab.

Down the track, **Rhythm Biosciences may seek TGA approval (i.e. inclusion on the ARTG as an In Vitro Diagnostic Medical Device¹⁵)** and this would cover non-laboratory users or environments not controlled by ISO 15189. **But the Company does not need ARTG inclusion to support the current business model** and it may find a sufficient business with having ColoSTAT offered as a lab-service only. Whether or not Rhythm Biosciences eventually seeks a more conventional TGA approval, it is not irrelevant to observe that approval through the NATA pathway is effectively a kind of TGA approval because NATA and the TGA collaborate¹⁶.

The Company is already laying the foundations for international expansion by securing early partnerships. In the UK, the NHS Southern Hub Research Team will evaluate ColoSTAT for suitability for general use over 2026. The Company will transfer relevant equipment and reagents to the laboratory for an independent evaluation of ColoSTAT in a laboratory with extensive

Rhythm Biosciences is on the market now, but it followed a different pathway than it pursued on its last attempt to get ColoSTAT to market.

Rhythm Biosciences is essentially following the same pathway as Lumos Diagnostics (ASX: LDX).

¹⁵ Australian Register of Therapeutic Goods.

¹⁶ Even in drugs or devices with conventional TGA approval, their laboratories and manufacturing facilities need to meet relevant ISO standards, and this is where NATA comes in.



experience in the assessment of bowel cancer screening clinical tests. In the first instance, analytical performance will be independently assessed followed by a further clinical evaluation in patients recruited for this purpose.

Rhythm Biosciences' management

The Company's current board and leadership composition is as follows (Figure 10):'

Figure 10: Rhythm Biosciences' leadership composition

Board of Directors & Management	
Name and Designation	Profile
David Atkins CEO	Dr Atkins is an accomplished global healthcare leader with global markets experience across a broad range of life sciences and healthcare disciplines, having gained deep experience in R&D, product development and commercialisation across biotech, medical device, IVD and data-driven solutions in all global markets. Over the last 30 years, David has held national, regional and global roles across the pharmaceutical, medical device and diagnostics sectors. David's responsibilities have covered all functions from discovery research through to sales and marketing in most key geographies. He has valuable experience in start-up ventures, scale-ups, turnarounds and high-growth enterprises. He has held senior leadership roles in smaller businesses including Congenica (UK), Veridex (US) and Gene Shears (Australia), and larger global businesses including Johnson & Johnson and Danaher.
Gavin Fox-Smith Non-Executive Chairman	Over his 38-year career Gavin has been a leader and champion of Medical Technology in Australia/NZ and Asia. He has also played lead Governance and Executive roles in Industry Bodies, Innovation Initiatives and Not for Profit Boards. Gavin is a strong advocate for Gender Equality and Indigenous Engagement. Gavin is Chair of ANDHealth (Australia's National Digital Health Initiative), Non-Executive Director for Omnigon, Bowel Cancer Australia and SAN Foundation. Gavin is a proud member of the Champions of Change Coalition Health group and serves as an Ambassador for Rotary Oceania Medical Aid for Children (ROMAC).
Sue MacLeman Non-Executive Director	Sue MacLeman has more than 30 years' experience as a pharmaceutical, biotechnology and medical technology executive having held senior roles in health administration, corporate, medical, commercial and business development. Sue has also served as CEO and Board member of several ASX, AIM and NASDAQ listed companies in the healthtech sector. She is a Non Executive Director on public, private and not for profit boards and is appointed to several academic, industry and government advisory boards and committees.
Andrea Steele General Counsel	Andrea Steele is an independent Melbourne based lawyer who specialises in providing legal, regulatory and compliance advice to the Australian life sciences, healthcare, energy and renewable industries. Andrea's key practice includes advising both listed and private companies, multinationals and government organisations on matters relating to the negotiation of complex commercial contracts, regulatory advice, major procurement, strategic collaborations and mergers and acquisitions. Andrea's deep experience and practical insights are particularly appreciated by clients who seek her guidance on how to plan and execute these important projects.



<p>Nir Dvorski Chief Operating Officer</p>	<p>Nir is an accomplished operational leader with over 25 years of experience in driving multidisciplinary teams toward successful product delivery across regulated and unregulated environments. His extensive experience spans the entire product lifecycle – from research to market adoption – across biotechnology, medical devices, defence, environment, telecommunication, and IT industries. Nir has delivered transformative solutions in cancer diagnostics, COVID point-of-care diagnostics, IVF technologies, diabetes management, hematology, and advanced pathology lab automation systems. Having worked with industry leaders including Planet Innovation, Invetech, Grey Innovation Group and Agilent Technologies, as well as founding several successful businesses, Nir brings comprehensive operational expertise in building robust business capabilities across commercial operations, customer delivery, product development, and manufacturing establishment.</p>
<p>Jackson Jones Chief Commercial Officer</p>	<p>Jackson is an experienced life science and biotechnology leader with over 25 years of experience in driving diagnostic innovation and commercialisation. His extensive technical expertise in cancer, proteomics, and molecular biology has been instrumental in successfully implementing market strategies across blood banking, microbiology, and infectious disease diagnostics.</p> <p>Jackson has demonstrated exceptional ability in guiding products through the complete lifecycle, from research and development through regulatory approvals to commercial success, with a proven track record of launching innovative diagnostic technologies across global markets including Australia, Asia, Europe, the UK, and the US.</p>
<p>Erika Spaeth Director of Clinical & Scientific Affairs</p>	<p>Dr. Spaeth has worked with the previous owner of GeneType™ since 2016. She is responsible for the development of clinical content and clinical rationale for the GeneType™ product suite. With a focus on transposing our cutting-edge approach to disease risk modelling into effortless yet actionable genetic-integrated information for both clinicians and patients, she is a cross-functional team member. Erika is involved in developing and executing commercial clinical research, pilot studies and managing academic research collaborations. She has wide experience in the high-complexity laboratory space from assay development to regulatory oversight of laboratory developed tests in the oncology, infectious disease and inherited disease space.</p>

Source: Company



Valuation of \$0.45-0.69 per share

We value Rhythm Biosciences at \$0.45 per share in a base case scenario and \$0.69 per share in an optimistic (or bull) case scenario.

We value Rhythm Biosciences at \$0.45 per share in a base case scenario and \$0.69 per share in an optimistic (or bull) case scenario. We have used a DCF methodology, modelling the Company as a combined group selling both GeneType and ColoSTAT rather than modelling the Company as a Sum of Parts. We have also assumed the Company continues to commercialise both, rather than licensing them out. This maximises the revenue that the Company would keep – a licensing deal would be unrealistic to see royalties of more than 20% although it might lead to a higher market penetration. For both GeneType and ColoSTAT we assumed commercialisation ramps up over the next few years, reaching the peak penetration 5 years from now (in FY31) and with stable population growth facilitating growth from peak penetration. Our specific assumptions for each product are as follows.

Genetype assumptions

We acknowledge that any market for GeneType is up for debate, but to make it easiest for investors, we went with the market that the Company has indicated it is targeting worldwide – 207m Normal Active Risk Assessors and 69m Higher Risk assessors. We did not geographically break any of this down but assumed a modest market penetration to compensate (Figure 11).

We used a GeneType Risk Test kit price of A\$399. This is not a figure regularly promoted in the Company's investor relations materials but is public data¹⁷. We would nonetheless observe that tests of this nature can vary based on several factors including whether the panel is single or multi-disease, the accreditation of the laboratory and whether or not counselling is needed. For comparison's sake, the Allelica Multi-Ancestry PRS test costs US\$349, US\$449 if a 30-minute consultation with a genetic counsellor is desired.

Figure 11: GeneType assumptions

GENETYPE Assumptions	Base Case	Bull Case
Potential market size (m)		
Higher risk	69.0	69.0
Lower risk	207.0	207.0
Population growth	2%	2%
Inflation growth	2%	2%
Peak penetration (Higher)	1.3%	1.5%
Peak penetration (Lower)	0.5%	0.8%
AUD/USD	0.65	0.65
Estimated pricing (A\$)	\$399	\$399

Source: Company

¹⁷ <https://optilabs.com.au/products/genetype-risk-test>



We assumed a higher penetration for Australia assuming it could play some part in the government screening program.

ColoSTAT assumptions

As per Figure 12 we have broken down the population sizes by geography, restricting it to Australia, the US and UK. We assumed a higher penetration for Australia assuming it could play some part in the government screening program, but even this could be underestimating its full potential. We assumed a A\$50 per test kit price in our base case and A\$60 in our bull case, as well as a 2% royalty on sales payable to the CSIRO.

Figure 12: ColoSTAT assumptions

ColoSTAT Assumptions	Base Case	Bull Case
Potential market size (m)		
AU	7.4	7.4
US	96.7	96.7
UK	20.8	20.8
Population growth	2%	2%
Inflation growth	2%	2%
Peak penetration (AU)	4.0%	5.0%
Peak penetration (US)	0.5%	0.8%
Peak penetration (UK)	1.0%	1.5%
AUD/USD	0.65	0.65
Royalty to CSIRO	2.0%	2.0%
Estimated pricing (A\$)	\$50	\$60

Source: Company

Corporate assumptions

- **Costs and margins.** We assumed at peak market penetration, the Company has a gross margin of 45% and a net margin of 20% which are in line with several advanced companies in this space including GRAIL, Trinity Biotech and Abbott Laboratories.
- **Funding.** We assumed no further funding is required beyond the capital raised in FY25.
- **Discount rate.** We used a discount rate of 14%, reflecting a 4% risk free rate of return, a 6.5% equity premium and a 1.5x beta.
- **Net cash position.** We modelled a net cash position of just over \$3m at the end of FY26.
- **Tax rate.** We used a 25% corporate tax rate in line with the rate for Australian companies with profits below A\$50m.
- **Terminal growth.** We included terminal growth – something we do not always do for biotech companies but have here because it is not the case that either GeneType or ColoSTAT will have a period of market exclusivity that will expire. We modelled a 2% rate.



Figure 13 shows our valuation summary and Figure 14 shows the sensitivity of our valuation to various WACCs.

Figure 13: DCF calculation

Valuation (A\$m)	Base Case	Bull case
Present Value of FCF	53.8	81.0
Present Value of Terminal Value	96.4	150.7
Enterprise Value (A\$ m)	150.2	231.7
Net (debt) cash	3.0	3.0
Equity value (A\$ m)	153.2	234.7
Share outstanding (Diluted)	338.6	338.6
Implied price (A\$ cents)	0.45	0.69
Current price (A\$ cents)	0.21	0.21
Upside (%)	120.6%	237.8%

Source: Pitt Street Research

Figure 14: Sensitivity analysis of DCF calculation (base case)

		WACC						
		11%	12%	13%	14%	15%	16%	17%
Terminal Rate	0.5%	0.57	0.51	0.45	0.42	0.37	0.33	0.30
	1.0%	0.60	0.52	0.47	0.43	0.37	0.34	0.31
	1.5%	0.62	0.54	0.48	0.44	0.38	0.35	0.31
	2.00%	0.64	0.56	0.49	0.45	0.39	0.35	0.32
	2.5%	0.67	0.58	0.51	0.47	0.40	0.36	0.33
	3.0%	0.71	0.61	0.53	0.48	0.42	0.37	0.33
	3.5%	0.74	0.63	0.55	0.50	0.43	0.38	0.34

Source: Pitt Street Research

We foresee the stock being re-rated to our valuation range driven by the following factors:

- Increased revenues from the continued rollout of ColoSTAT and GeneType
- The securing of partnerships to advance the development of ColoSTAT and GeneType including marketing and distribution agreements.
- Continued clinical work validating the efficacy of ColoSTAT and GeneType.



Risks

We see the following key risks to our investment thesis:

- **Funding risk:** The Company is not profitable and may need further capital raisings to guide both ColoSTAT and GeneType to levels of commercialisation whereby they can sustain the Company. Raising capital, particularly on favourable terms, can be a challenge for the Company.
- **Regulatory risk.** The Company's ability to commercialise its product is contingent on regulators maintaining approval where it already exists (including meeting ongoing regulatory compliance requirements) and giving approval to new products. A failure to give new products approval, or even a withdrawal of approval, could be catastrophic to its future ambitions.
- **Commercial risk.** There is the risk that the Company may fail to execute its commercial objectives for a variety of reasons including either of the above reasons, or an inability to secure partnerships, failure of relationships with service providers, technical difficulties of various kinds (such as manufacturing difficulties or cybersecurity breaches) competition. Our investment thesis is predicated on everything going smoothly.
- **Key personnel risk:** There is the risk that the Company may lose key personnel and be unable to replace them and/or their contribution to the business



Appendix I – Glossary

Body Mass Index (BMI) - A numerical measure calculated from a person's height and weight that is commonly used to classify body weight status (such as underweight, healthy weight, overweight or obese) and to help assess risk for various diseases.

BRCA genes (BRCA1 and BRCA2) - Genes involved in repairing damaged DNA. Inherited mutations in these genes significantly increase the risk of breast, ovarian and some other cancers, but they account for only a small proportion of total cancer cases.

Cells - The smallest living units of the body that carry out all biological functions. Cells contain DNA and work together to form tissues and organs.

Colorectal - A term referring collectively to the colon and rectum, which are parts of the large intestine.

Colorectal cancer - A cancer that begins in the colon or rectum, often developing from precancerous growths called polyps and commonly influenced by a combination of genetic, lifestyle and environmental factors.

CSIRO (Commonwealth Scientific and Industrial Research Organisation) - Australia's national science agency, conducting research across health, agriculture, industry and the environment, including genomics and medical technologies.

Diabetes - A chronic metabolic disease characterised by high blood glucose levels, most commonly Type 2 diabetes, which results from insulin resistance and is influenced by genetic and lifestyle factors.

Faecal Immunochemical Test (FIT) - A stool-based screening test that detects human blood in faeces using antibodies, commonly used in colorectal cancer screening programs because it is specific to bleeding from the lower gastrointestinal tract.

Faecal Occult Blood Tests (FOBTs) - A group of stool tests designed to detect hidden (occult) blood in faeces, used for colorectal cancer screening. These include older chemical-based tests and newer immunochemical tests such as FIT.

Genome - The complete set of genetic material (DNA) in an organism, containing all the instructions needed for growth, development and biological function.

NATA (National Association of Testing Authorities) - Australia's national accreditation body that assesses and accredits laboratories, inspection bodies and testing facilities to ensure they meet international quality and competence standards.

Pathology - The medical specialty that studies disease by examining tissues, blood, bodily fluids and other samples to support diagnosis, prognosis and treatment decisions.

Polygenic Risk Score (PRS) - A numerical estimate of an individual's genetic predisposition to a disease, calculated by combining the effects of many common genetic variants across the genome, each contributing a small amount of risk.

Proteins - Large, complex molecules made from amino acids that perform most of the body's functions, including structural support, chemical reactions, signalling and immune responses.

Proteome - The complete set of proteins produced by a cell, tissue or organism at a given time, reflecting how genetic information is actively expressed in biological processes.



RNA (Ribonucleic Acid) - A molecule derived from DNA that carries instructions for making proteins and plays key roles in regulating gene expression and cellular function.

SNP (Single Nucleotide Polymorphism) technology - A genetic analysis approach that identifies single-letter variations in DNA between individuals. SNPs are the most common type of genetic variation and are widely used in disease risk prediction.

Triage test - A test used to prioritise individuals for further diagnostic investigation by identifying those most likely to benefit from follow-up testing, helping allocate healthcare resources efficiently.

Appendix II – Capital Structure

Class	In Millions	% of dully diluted
Ordinary shares	337,011,420	76%
Options	107,366,680	24%
Performance shares	0	0%
Fully diluted shares	444,378,100	

Source: Company



Appendix III – Analysts' Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018 and the designation of Financial Modelling & Valuation Analyst by the Corporate Finance Institute. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms

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