



## ColoSTAT's rollout is ramping up!

The dream Rhythm Biosciences (ASX:RHY) investors have held ever since the company listed in 2017 has been realised: ColoSTAT has been approved and commercialised, even if slightly different to what investors may have earlier anticipated.

### The ColoSTAT rollout has begun

Rhythm Biosciences completed the first sale of ColoSTAT earlier this month, which represented not only validation of ColoSTAT itself, but also the entire customer pathway – specifically the sample collection, logistics, assay processing, and reporting of the results; proving it all functions effectively. ColoSTAT's coming to market has been made possible by NATA accreditation last week, which is effectively a kind of TGA approval and is a similar pathway to what Lumos Diagnostics pursued with its FebriDx test. This is in addition to the November 2025, accreditation of RHY's laboratory. Taken together, customers can be reassured that the lab and ColoSTAT clinical test meets the highest international standards for analytical quality, laboratory competence, and results traceability.

### The rollout will speed up in the coming weeks

Rhythm expects ColoSTAT adoption to speed up from here. 4Cyte will promote the test across its network of clinicians and Rhythm will have sales representatives of its own promoting ColoSTAT. There is a base capacity of processing \$4m worth of tests in a year and the company's TAM in Australia is 500,000 patients per year. There has been significant interest based on the large pool of clinicians participating in the Access Program the company has been running. And the company believes, given the compelling economic value proposition in a reduction of unnecessary colonoscopies, ColoSTAT could be on the MBS within 2-3 years.

### Valuation range of A\$0.45-0.69 per share

We continue to 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. Please see page 8 for further details on our valuation and page 10 for the key risks associated with our thesis.

Share Price: A\$0.21

ASX: RHY

Sector: Healthcare and Life Sciences

18 March 2026

Market cap. (A\$ m)	71.1
# shares outstanding (m)	338.6
# shares fully diluted (m)	446.0
Market cap ful. dil. (A\$ m)	93.6
Free float	100%
52-week high/low (A\$)	0.255 / 0.051
Avg. 12M daily volume ('000)	591.9
Website	<a href="https://rhythmbio.com">https://rhythmbio.com</a>

Source: Company, Pitt Street Research

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



Source: Refinitiv Eikon, Pitt Street Research

<b>Valuation metrics</b>	
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 progress Rhythm has made with ColoSTAT to date

*But this report will focus particularly on ColoSTAT considering the strides that have been made in recent weeks in obtaining regulatory approval and signing the first customer.*

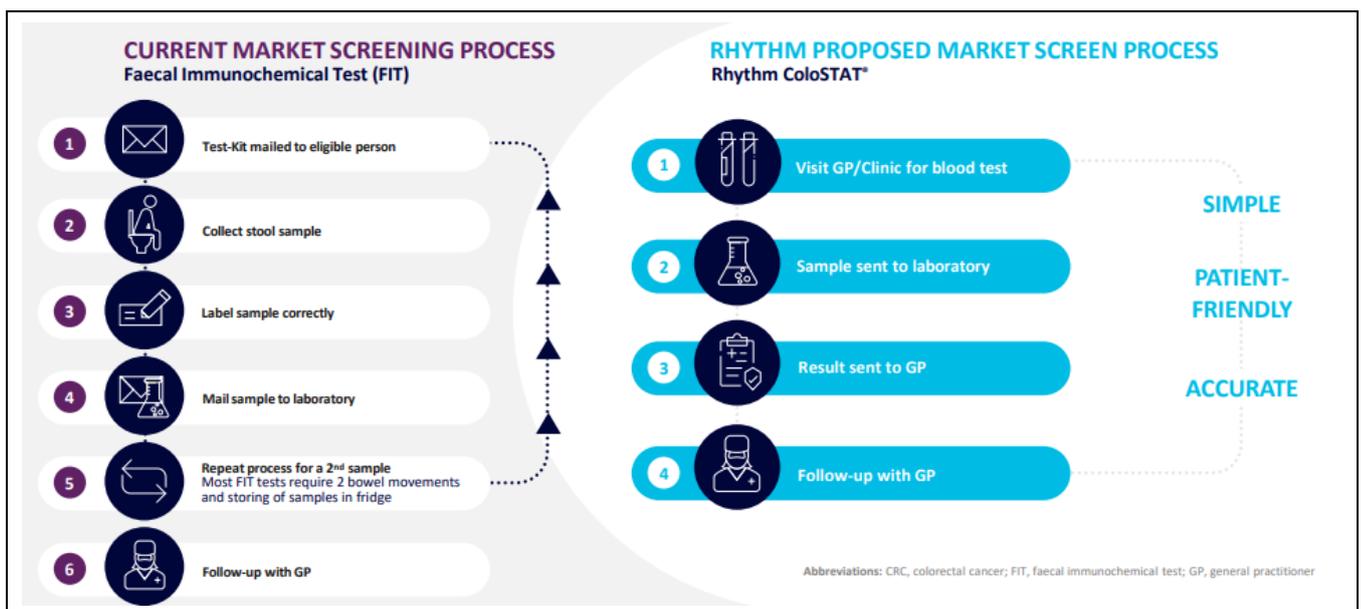
ColoSTAT is Rhythm’s blood test that generates a colorectal cancer risk score based on the measurement of particular protein levels in the patient’s blood. Investors new to the Rhythm story should view our February reinitiation report on the company for full details on ColoSTAT, how it works, the value proposition and the market opportunity, as well as the opportunity the company has in GeneType. But this report will focus particularly on ColoSTAT considering the strides that have been made in recent weeks in obtaining regulatory approval and signing the first customer.

The hope for investors that bought at Rhythm’s IPO and up until late 2023 was that ColoSTAT would receive conventional TGA approval and go on to replace the Faecal Immunochemical Test (FIT) used in Australia’s bowel cancer screening program. There has never been a shadow of a doubt that ColoSTAT:

- Has efficacy above and beyond alternatives (The most recent study depicted 81% sensitivity and 91% specificity, not to mention a 99% Negative Predictive Value <sup>1</sup>),
- Is a simpler and less nauseating process, thus more likely to be preferred by patients (Figure 1),
- Is lower cost,
- Can operate at scale, and
- Given all the reasons above could increase bowel cancer screening rates.

In late 2023, investors could have been forgiven for thinking it was all over when the company made an application to the TGA and then withdrew it following regulatory feedback because more independent production batches were needed than the Company possessed at that time.

Figure 1: FIT vs ColoSTAT



Source: Company

<sup>1</sup> The probability that a person with a negative result will not have the disease.



## Late 2025 and early 2026 has seen regulatory approval

In December 2025, Rhythm's Melbourne lab obtained NATA certification. 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. Rhythm was offering ColoSTAT for use in individuals with symptoms consistent with colorectal cancer, particularly where stool-based testing is unsuitable or not preferred, although doctors had to use their own personal judgement on the test. Nonetheless, this did not stop the company signing a distribution deal with 4Cyte Pathology, one of Australia's biggest players, and from signing its first customer.

*The NATA approval Rhythm's lab and ColoSTAT have received are the most rigorous form of independent validation available for a clinical diagnostic service in Australia.*

In March, Rhythm obtained a variation-to-scope assessment whereby ColoSTAT itself was approved within the company's accredited laboratory services. To use the analogy of a bakery: the company's 'oven' (the lab) was confirmed as the highest quality the prior December, but now all the bread (Rhythm's tests) generated from the oven (the lab) was confirmed. Indeed, the NATA green light was confirmation that ColoSTAT meets the highest internationally recognised standards for analytical quality, laboratory competence and result traceability in medical testing. This may not have been the kind of approval investors may have been expecting, but NATA approval is the most rigorous form of independent validation available for a clinical diagnostic service in Australia. Not just a check, but a confirmation that the science and technical competence is more than sufficient to have real confidence.

## Initial customer adoption has occurred and will ramp up quickly

In the same week the company announced the approval, the first sale occurred. The sample was collected by 4Cyte pathology, transported to RHY's clinical laboratory, processed using assay and a result was reported to the ordering clinician. This was more than a symbolic milestone; it was a confirmation that the full pathway was good. The sample collection, logistics, assay processing and result reporting was all functioning effectively.

*The first sale of ColoSTAT occurred and the company plans to scale further from here.*

The company believes it can scale quickly, not just because the process has been confirmed but also because of the interest it has received. The company's key to expansion will be its Access Program. 7 participants signed up for it and the company plans to reach 20 before the end of March. 5 sites in 3 weeks have been officially onboarded, with 30 physicians being engaged with only one of which (a surgeon who was a referral site for cancer patients) declined to participate. Volumes will grow over time as physicians continue to engage with ColoSTAT. 4Cyte will promote the test across its network of clinicians and will support the volume that we generate directly. Rhythm expects to have approximately 20 reps selling ColoSTAT across Australia's East Coast in a few weeks.



*Rhythm has a base capacity without doing anything further of processing \$4m of tests in a year.*

## The broader opportunity and the key to further growth

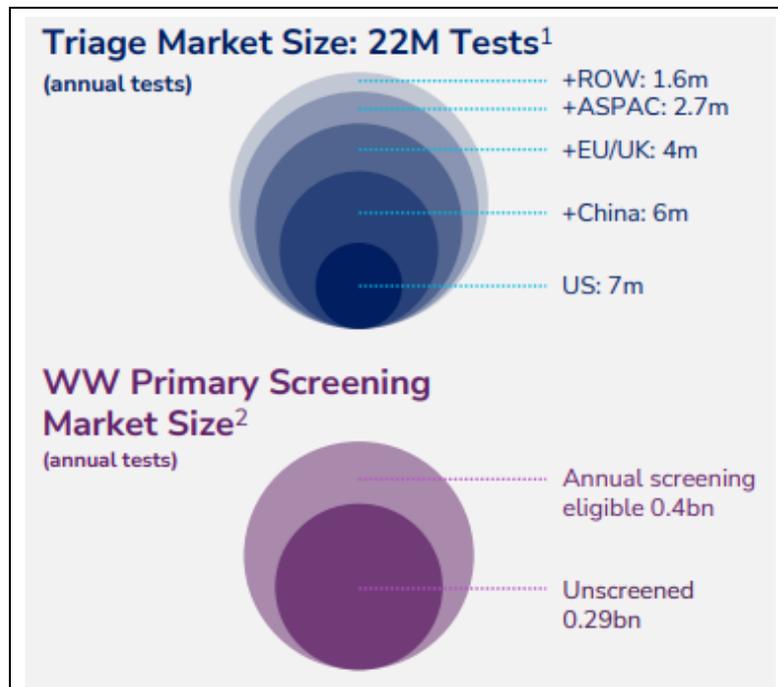
Rhythm has a base capacity without doing anything further of processing \$4m of tests in a year (assuming a 200-day work year). The company has a TAM for Australia in the region of 500,000 patients per year and scale this easily (Figure 2).

Investors may be wondering if ColoSTAT can get formal de Novo TGA approval and/or an MBS listing. First, we would note that Rhythm may find it has sufficient business just in its current scope. Nonetheless, the company has begun the process to list on the MBS because it would cover non-laboratory users or environments not controlled by ISO 15189 and this would unlock the full market potential. The company believes it has a compelling enough value proposition that it may be on the MBS within 2-3 years, well ahead of the average time to be adopted by the MBS.

Rhythm also has ambitions to expand overseas, starting in the UK where it is collaborating with the NHS Southern Hub Research Team which 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 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.

Overall, Rhythm believes there is a market size of nearly 300 million based on the annual eligible screening population and the proportion of the population that goes unscreened. This would amount to 22 million annual tests<sup>2</sup>.

Figure 2: The global ColoSTAT market



Source: Company

<sup>2</sup> Based on 40% of worldwide colonoscopies.



### The value proposition with ColoSTAT

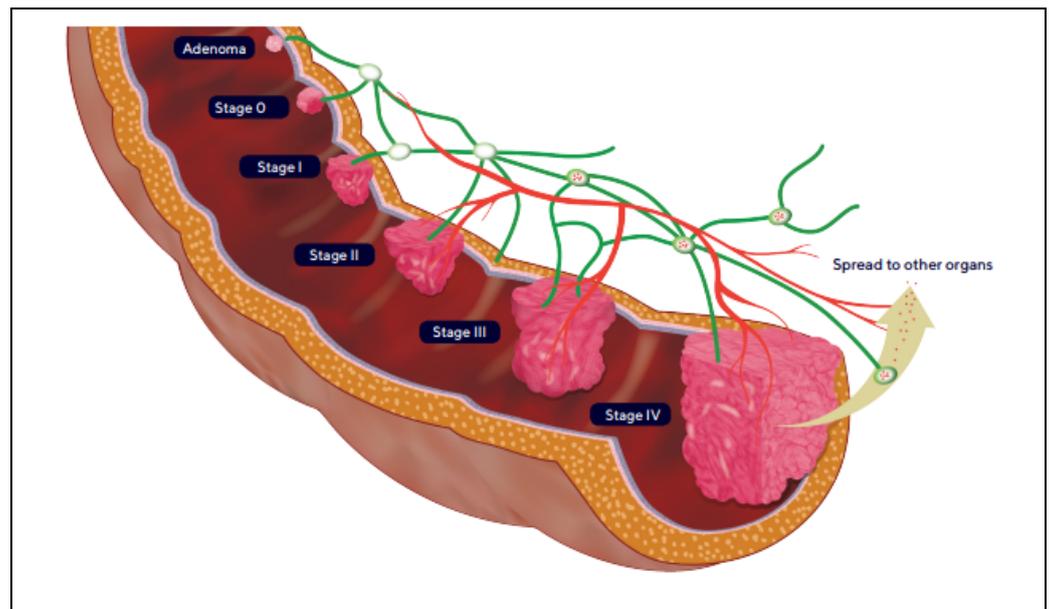
*ColoSTAT may not replace FIT (at least altogether) but complement it to identify patients who genuinely need colonoscopies and those who do not.*

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 should be prioritised for colonoscopies as well as rule out those who have no need for them at all (if you are negative, there is 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). Also remember that FIT is only mailed every two years, so ColoSTAT could be recommended if a doctor thinks their patient should not wait for testing or if the FIT is unappealing in the first place.

As we discussed in our initiation note, colorectal cancer is more challenging to detect until later stages when treatment may be difficult (if indeed possible at all) as external signs such as blood in the stool may not be present until later, so it is important that screening is done earlier (Figure 3). With a government-funded screening program, it is difficult in one sense to comprehend how participation rates are less than 50%, although when one remembers the cumbersome and nauseating nature of the FIT it is more understandable. Modelling has shown that even if participation rose to 60%, bowel cancer deaths would drop dramatically<sup>3</sup> (Figure 4). ColoSTAT could play a major role in the Australian government increasing bowel cancer screening and reducing deaths from the disease.

Figure 3: The stages of colorectal cancer and their visibility

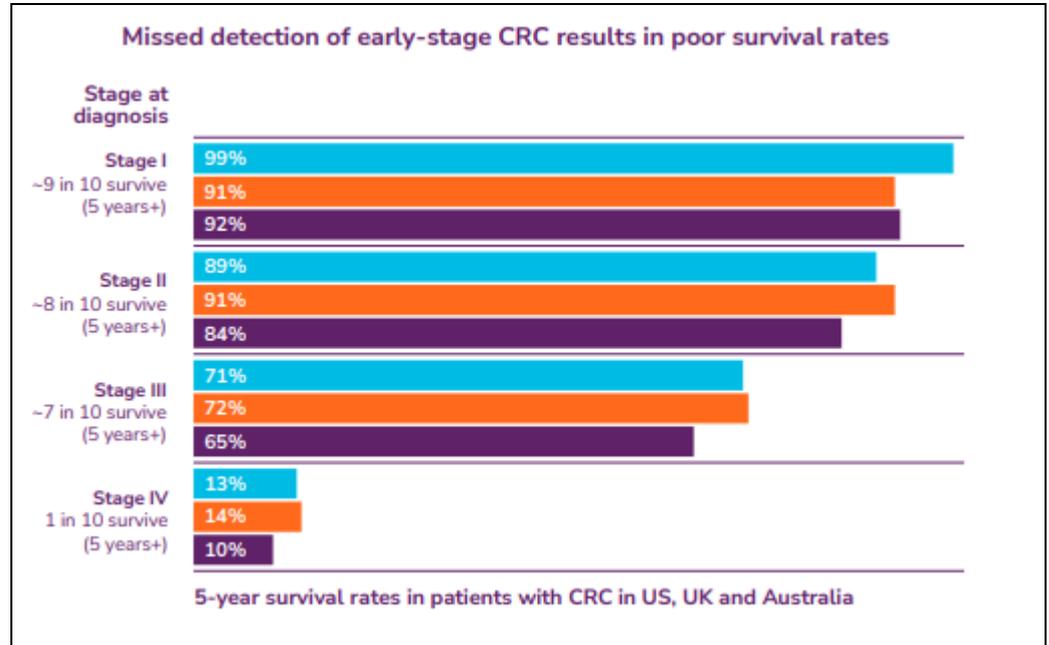


Source: Company

<sup>3</sup> 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/>



Figure 4: Result of earlier detection on survival rates



Source: Company

### Rhythm’s opportunity with GeneType

In late 2024, Rhythm picked up GeneType after its original owner Genetic Technologies went into administration. 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. 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. The idea is that it could be used by patients known to be at a higher risk, but also lower risk individuals taking proactive steps to monitor their health.

We noted in our initiation report that this could ultimately be a greater revenue maker than ColoSTAT, and in fact, the company derived revenues from GeneType first. 2025 saw these revenues, a legacy of the work Genetic Technologies did in years gone by, as well as several strategic agreements to facilitate the rollout of GeneType across various platforms including through pathology services and through cancer education providers.

For the moment, investors will be more excited about ColoSTAT because we will see faster revenue growth there thanks to the expanded NATA scope. In the longer-run, GeneType could derive more revenue given its higher market potential, by virtue of being applicable for a longer list of conditions. As with ColoSTAT, the key will be generating those revenues.

*GeneType could derive more revenue given its higher market potential, by virtue of being applicable for a longer list of conditions.*



## Valuation of \$0.45-0.69 per share reiterated

*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 reiterate our 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. Our methodology is DCF modelling the company as one rather than as a sum of the parts. We assumed the company commercialises both ColoSTAT and GeneType in its own right rather than licensing them. 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. Readers should view Figure 5 and Figure 6 for our specific growth assumptions for both products and our initiation note for further details on them.

Figure 5: GeneType assumptions

GENETYPE Assumptions	Base Case	Bull Case
<b>Potential market size (m)</b>		
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

Figure 6: ColoSTAT assumptions

ColoSTAT Assumptions	Base Case	Bull Case
<b>Potential market size (m)</b>		
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 7 shows our valuation summary and Figure 8 shows the sensitivity of our valuation to various WACCs.

Figure 7: 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
<b>Enterprise Value (A\$ m)</b>	<b>150.2</b>	<b>231.7</b>
Net (debt) cash	3.0	3.0
<b>Equity value (A\$ m)</b>	<b>153.2</b>	<b>234.7</b>
Share outstanding (Diluted)	338.6	338.6
<b>Implied price (A\$ cents)</b>	<b>0.45</b>	<b>0.69</b>
Current price (A\$ cents)	0.21	0.21
Upside (%)	114.3%	228.6%

Estimates: Pitt Street Research

Figure 8: 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	<b>0.45</b>	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

Estimates: Pitt Street Research



## Catalysts for a re-rating

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 facing Rhythm Biosciences

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 – 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 II – 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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