ASX Announcement
21st January 2026

Landmark Publication Validates ColoSTAT® Clinical Performance

Highlights

- ✓ First peer-reviewed publication validates the first generation ColoSTAT® clinical performance with **81.3% sensitivity and 91% specificity** – performance comparable to stool-based tests used in Australia's National Bowel Cancer Screening Program.
- ✓ Addresses immediate commercial opportunity: **Australia's symptomatic patient market represents ~800,000 annual colonoscopy referrals**.
- ✓ Clear competitive advantage: **Simple blood test could overcome +50% non-compliance** associated with stool-based screening; convenient patient experience drives higher uptake if subsequent studies confirm published results.
- ✓ Health system value proposition: **Efficient triage could reduce unnecessary colonoscopies by up to 50%**, delivering significant cost savings (colonoscopy costs A$1,000-A$4,500 per procedure) while maintaining patient safety.
- ✓ Robust clinical validation: **989 patients across multiple centres** provides a strong foundation for regulatory approvals and commercial partnerships.

Melbourne, Australia, 21st January 2026: Rhythm Biosciences Ltd ('**RHY**', the '**Company**' or the '**Group**') (**ASX: RHY**), a transformative, predictive cancer diagnostics technology company is pleased to announce the publication of landmark clinical validation data for its first generation ColoSTAT® ("ColoSTAT®S" - singleplex) blood test in the peer-reviewed *Journal of Gastrointestinal Cancer*. This publication marks a significant milestone, providing independent scientific validation that also positions the optimised second generation multiplex ColoSTAT® ("ColoSTAT®M" - multiplex) for near-term commercialisation in the symptomatic patient triage market.

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The study evaluated ColoSTAT®S's performance in 989 patients across multiple clinical centres, demonstrating 81.3% sensitivity for detecting colorectal cancer with 91% specificity – performance metrics that favourably rival established stool-based tests while offering significantly improved patient convenience and compliance potential.

A Summary of Major Benefits / Conclusions include:

1. **Immediate Commercial Opportunity - *Symptomatic Patient Market***
2. **Critical Clinical Capability - *Distinguishing Cancer from Benign Conditions***
3. **Competitive Advantage - *Blood-Based Testing Drives Compliance***
4. **Health System Value - *Reducing Unnecessary Procedures***
5. **Path to Commercialisation - *Near-Term Revenue Opportunity***

More on the Above:

1. Immediate Commercial Opportunity - *Symptomatic Patient Market*

The publication validates ColoSTAT®'s biomarkers for immediate application in improving prioritisation or triaging patients with symptoms of CRC such as rectal bleeding, abdominal pain, or changes in bowel habits. In Australia alone, approximately 800,000 colonoscopies are performed annually for symptomatic investigation, yet fewer than 5% reveal cancer. By efficiently identifying high-risk patients requiring urgent colonoscopy versus lower-risk patients suitable for watchful waiting, ColoSTAT® addresses a critical unmet need with clear health economic benefits.

Globally, the colorectal cancer diagnostics market exceeds US$8 billion annually and is projected to grow at 7-9% CAGR driven by aging populations, increasing screening awareness and demand for non-invasive testing options. The symptomatic patient segment represents an immediate, addressable market opportunity that requires less regulatory burden than population screening applications.

2. Critical Clinical Capability - *Distinguishing Cancer from Benign Conditions*

"Importantly, this study demonstrated for the first time that ColoSTAT®S can differentiate between bowel cancer patients and patients presenting with other, non-cancer causes of gastrointestinal symptoms. This test should enhance our ability to identify those patients with common colorectal symptoms, such as altered bowel habit or diarrhoea, who may have colorectal cancer as the cause and

may offer an alternative to faecal testing as a screen for colorectal cancer in people who are averse to stool tests," said Prof Finlay Macrae, a senior investigator on the study.

This capability is commercially significant as it demonstrates ColoSTAT®'s clinical utility beyond simple cancer detection – it can effectively triage patients with overlapping symptoms, a challenge that drives substantial healthcare costs and patient anxiety. ColoSTAT®S's ability to maintain high specificity while distinguishing cancer from these benign conditions represents a meaningful clinical advance.

3. Competitive Advantage - *Blood-Based Testing Drives Compliance*

Current colorectal cancer screening in Australia relies primarily on faecal immunochemical tests (FIT), which suffer from +50% non-participation rates in the National Bowel Cancer Screening Program. Patient surveys consistently identify the collection method as a primary barrier to compliance. Conversely, patient surveys have demonstrated that a simple blood draw, as used with ColoSTAT®, offers a more acceptable alternative, potentially driving significantly higher screening uptake.

With performance parameters favourably comparing against established stool-based tests (sensitivity 74% – 93%, specificity 85-96% reported in literature) but offering superior patient convenience, ColoSTAT® is well-positioned, subject to further, large scale studies, to capture market share as healthcare systems prioritise patient-centric approaches and seek to improve screening participation rates.

4. Health System Value - *Reducing Unnecessary Procedures*

Colonoscopy is the accepted gold standard diagnostic procedure; however, it does carry risks and significant costs (A$1,000-$4,500 per procedure). In symptomatic populations where the cancer detection rate is <5%, a substantial proportion of colonoscopies yield negative results. By accurately triaging patients, ColoSTAT® could reduce or delay unnecessary colonoscopy referrals while maintaining patient safety through high sensitivity for cancer detection.

For Australia's public health system alone, this efficiency gain could deliver significant annual savings while simultaneously reducing patient exposure to procedural risks and improving resource allocation for genuinely high-risk patients. This value proposition creates a compelling case for reimbursement and payer support.

5. Path to Commercialisation - *Near-Term Revenue Opportunity*

"These results support the use case of applying ColoSTAT® to the triage of patients with gastrointestinal symptoms to colonoscopy as an early commercial application with benefits anticipated for both the patients and the health system more broadly," Rhythm CEO, Dr David Atkins said. *"Since the completion of this study with the 1st generation ColoSTAT (ColoSTAT®S) we have used the same biomarkers in a re-engineered, multiplexed version of the test (ColoSTAT®M) that will be the focus of our commercial activity."*

The Company's strategy prioritises the symptomatic patient market as the initial commercial target and as previously announced, will be leveraging its ISO15189 status to launch the multiplex version of ColoSTAT® (ColoSTAT®M). As well as supporting sales, this path will allow collection of additional clinical evidence required by the TGA and their international peers to support ColoSTAT® use in new clinical indications like general population screening.

Looking Ahead: Building on Clinical Validation

This publication represents a pivotal milestone for Rhythm Biosciences, providing peer-reviewed validation of the clinical performance of ColoSTAT®S and establishing the scientific foundation for commercialisation of ColoSTAT®M. The Company is now focused on:

- Implementing the ColoSTAT® Access Program in Australia.
- Establishing commercial partnerships for manufacturing and distribution.
- Developing health economic models to support reimbursement applications.
- Continuing broader screening validation studies to support expanded market applications.

[1.] He EY, van Hazel GA, Sloss AM, Pianko S, Brown GJ, Clingan PR, Singh R, Solterbeck AC, Traficante R, Formby-Miller L, Lockett T, Macrae F. A Prospective, Cross-Sectional, Multicenter Study Evaluating a Multi-Target Blood Protein in Vitro Diagnostic Test for Colorectal Cancer. J Gastrointest Cancer. 2026 Jan 16;57(1):19. doi: 10.1007/s12029-025-01373-y. PMID: 41543810; PMCID: PMC12811346.

A copy of this publication can be accessed here.

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This announcement was authorised by the Board of Directors of Rhythm Biosciences Limited.

For further information contact us via investors@rhythmbio.com.

About Rhythm Biosciences

Rhythm Biosciences Ltd (ASX: RHY) is an Australian innovative, medical diagnostics company aimed at delivering simple, affordable blood tests for accurate and early detection of cancers. Rhythm is focused on improving patient outcomes through detection at the earliest possible stage, reducing the global burden of cancer, and saving lives. Rhythm Biosciences is committed to working with likeminded global partners to achieve commercialisation and distribution of these simple solutions. The company was founded in 2017 and is headquartered in Melbourne, Australia. For more information, visit rhythmbio.com and follow the company on LinkedIn and X.

About ColoSTAT®

Colorectal cancer (CRC), also referred to as bowel cancer, is the second leading cause of cancer deaths globally. If diagnosed early, colorectal cancer can be curable. The ColoSTAT® Test is Rhythm Bioscience's simple blood-based test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood of CRC. It is intended for individuals with symptoms associated with Colorectal Cancer (CRC). The ColoSTAT® Test is based on research from Australia's CSIRO and is patent protected internationally. It has the potential to play a key role in reducing the mortality rate and healthcare costs associated with colorectal cancer.

About geneType™

geneType™ is a sophisticated genetic risk assessment testing platform that combines clinical, family history and genetic data to provide comprehensive risk assessments for various diseases. The platform leverages polygenic risk scores and clinical risk factors to generate personalized health insights, helping individuals and healthcare providers make more informed medical decisions. The technology allows for risk assessment across multiple conditions including breast cancer, cardiovascular disease, diabetes, colorectal cancer, prostate cancer, and melanoma. The tests are delivered through healthcare providers and genetic counsellors, ensuring appropriate clinical oversight and support for patients receiving their results. The platform's multi-disease assessment capabilities and clinical utility position it well to capture growing demand in the preventative healthcare and precision medicine markets. For more information, please visit www.genetype.com.