ASX Announcement
22nd September 2026

Completion of First Phase of ColoSTAT® Assessment by NHS Laboratory – Technology Transfer Supports Pathway to International Markets

Highlights

- ✓ **The Southern Hub research laboratory based at the Royal Surrey NHS Foundation Trust has successfully completed technology transfer of ColoSTAT®**
- ✓ **This completes the first phase of the independent evaluation of ColoSTAT® announced to the market on 10 December 2025**
- ✓ **The next phase is analytical evaluation of the assay in the Hub laboratory, followed by a clinical study**
- ✓ **A successful analytical evaluation would allow the program to progress to a clinical study which, if successful, would provide independent clinical performance data for ColoSTAT® in an NHS laboratory setting**
- ✓ **Demonstrating that ColoSTAT® can be transferred to and operated by a third-party laboratory supports the Company's strategy to pursue laboratory partnerships in other key international markets**

Melbourne, Australia, 22nd September 2026: Rhythm Biosciences Ltd ('**RHY**', the '**Company**' or the '**Group**') (**ASX: RHY**), a transformative, predictive cancer diagnostics technology company, is pleased to announce that the Southern Hub Research Team based at the Royal Surrey NHS Foundation Trust and part of the NHS Berkshire and Surrey Pathology Services network ('the **Hub**') in England has successfully completed the technology transfer of ColoSTAT®, the Company's blood-based test for the detection of bowel cancer. The Hub team are now able to run the ColoSTAT® assay themselves, in their own laboratory, using the Company's system and reagents.

Building on Previously Announced NHS Engagement

As announced to the market in December 2025, the Hub agreed to evaluate ColoSTAT® in its own laboratory as part of its ongoing assessment of potential clinical assays that could be used in early diagnosis of bowel (colorectal) cancer. Previously, Rhythm set out the clinical evaluation plan for that work involving technology transfer, analytical validation and clinical evaluation. With the first phase now complete, the Hub expects to commence analytical evaluation immediately, with the clinical study to follow.

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What Has Been Completed

The first goal of the program was to transfer a complete ColoSTAT® system and reagents to the Hub laboratory, and to have the Hub team run the assay themselves in their laboratory. This involved the Hub team testing standards and controls (reference samples with known results) supplied by the Company and this phase is now complete.

Technology transfer is a necessary step for any diagnostic test intended to be run in laboratories other than the developer's own. Successful completion of this phase demonstrates that the ColoSTAT® assay can be transferred from Rhythm's own laboratory environment and established and operated by an external laboratory team. This is an important capability for the Company's laboratory-partnership commercialisation model.

Why the Southern Hub Matters

The Southern Hub is involved in research that has informed how the faecal immunochemical test (FIT) is used in both screening and symptomatic pathways and has scientific expertise to explore novel biomarkers like those that underpin ColoSTAT®'s performance.

The NHS Bowel Cancer Screening Programme[1] offers a stool-based test every two years to those aged 50 to 74, issuing approximately 8 million invitations in 2024–25 with approximately 65% uptake. A significant number of bowel cancer diagnoses continue to occur through the symptomatic pathway, and the NHS National Cancer Plan contemplates changes to increase the sensitivity of bowel cancer testing — changes that could place further pressure on endoscopy capacity. ColoSTAT® has the potential to play a role in the symptomatic pathway, including as a simple blood test for symptomatic individuals who are unwilling or unable to complete stool-based testing, and as a triage tool to help prioritise colonoscopy capacity.

Next Phases — Analytical Evaluation and Clinical Study

The next phase is analytical evaluation, in which the Hub team will run ColoSTAT® on patient clinical samples in its own laboratory to confirm the assay performs reliably and consistently in their hands. If successful, the program would then progress to a larger, prospective clinical study, designed to generate independent data on how accurately ColoSTAT® detects bowel cancer in an NHS laboratory setting.

It is important to note that the timing, scope and outcome of the analytical evaluation and clinical study are determined by the Hub and are not within the Company's control. There is no certainty that either phase will be successful, or that the evaluation will result in adoption of ColoSTAT® by the NHS, or in any commercial arrangement. Rhythm will update the market on material developments in accordance with its continuous disclosure obligations.

Significance for ColoSTAT® – Opportunity Beyond Australia

ColoSTAT® was launched in Australia as a clinical service for the domestic patient population. The Company estimates this Australian opportunity at approximately 200,000 tests[2] per year, based on the estimated share of colonoscopies performed in Australia each year that are diagnostic.

However, Australia is generally considered to represent only around 2% of the global healthcare market. Having now completed its first transfer of the ColoSTAT® assay to an independent laboratory, the Company believes it is better positioned to pursue laboratory partnerships in additional geographies, subject to local regulatory approvals, reimbursement and suitable commercial arrangements.

"Getting a new clinical diagnostic running in someone else's laboratory, to their standards, with their people, is a critical step in taking a test beyond a single laboratory and into new markets. The Hub team, led by Professor Sally Benton, are now running ColoSTAT® themselves, which is exactly what we set out to achieve in this first phase. Attention now turns to the next stage of the Hub's evaluation," said Dr David Atkins, Managing Director and Chief Executive Officer of Rhythm.

Professor Sally Benton, Consultant Clinical Biochemist and Hub Director, commented: "We are continuously searching for ways to improve our diagnostic pathway for bowel cancer. We are very excited to now have the ColoSTAT® equipment in our laboratory and look forward to the next stages of this project and the results it will generate."

1. www.gov.uk/government/statistics/bowel-cancer-screening-annual-report-2024-to-2025
2. AIHW; Gastroenterological Society of Australia; Cancer Council Australia, NBCSP Monitoring Report June 2025 and Company estimates.

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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 like-minded 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 Biosciences' 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 personalised 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.