

## **Rhythm Initiates Commercialisation of ColoSTAT® Following Updated Laboratory ISO15189:2022 Accreditation**

### **Highlights**

- ✓ **Rhythm has commenced commercialisation of ColoSTAT®, following the update and renewal of the Company's ISO15189:2022 accreditation, marking its transition to first market launch.**
- ✓ **ColoSTAT® will initially be offered as a blood-based diagnostic alternative for symptomatic individuals where stool-based testing is unsuitable, unavailable, or not preferred, addressing a significant unmet clinical need.**
- ✓ **ColoSTAT® will be provided as a clinical laboratory service through Rhythm's Melbourne-based certified laboratory, with domestic market rollout and clinician activities beginning immediately.**

**Melbourne, Australia, 12th December 2025:** Rhythm Biosciences Ltd ('RHY', the 'Company' or the 'Group') (ASX:RHY), a transformative, predictive cancer diagnostics technology company, is pleased to announce the initiation of commercialisation activities for ColoSTAT®, its flagship blood-based colorectal cancer (CRC) test. This follows the Company's recently updated ISO15189:2022 accreditation and represents a major milestone.

ColoSTAT® will initially be offered for use in individuals who exhibit symptoms consistent with CRC, particularly where stool-based testing (the FIT test) is unsuitable or not preferred. This provides clinicians with an alternative pathway during periods of watchful waiting or in circumstances where stool-based screening cannot be completed.

Commercialisation will begin with the ColoSTAT® *Access Program* which will include selected clinical leaders who will be supported by Rhythm to offer ColoSTAT® to symptomatic individuals. This initiative is designed to support clinician experience with the test, generate additional real-world data, and further strengthen the existing evidence base as Rhythm prepares for broader market penetration.

Consistent with Rhythm's commitment to quality and regulatory compliance, the Company will proceed with a variation to scope assessment with the National Association of Testing Authorities (NATA) scheduled for January 23rd, 2026. Successful completion of this assessment would formally establish ColoSTAT® as an accredited laboratory service, supporting clinician confidence and commercial scalability.

**Directors**

Dr. David Atkins, CEO & MD commented that, “This is welcome news for the many individuals in Australia who are unable or unwilling to use the current gold standard for bowel cancer detection.”

Rhythm Chairman, Gavin Fox-Smith added, “Initiating the commercialising of ColoSTAT® before the end of 2025 has been a consistent and visible milestone communicated by the team and I’m delighted to see the business continue to meet its commitments”.

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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](mailto: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](http://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. The ColoSTAT® Test is intended for Clinical Evaluation until the completion of the NATA review scheduled to commence on 23rd January 2026.

#### **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](http://www.genetype.com).