

ColoSTAT® Kit enters Final Phase Pre-Commercialisation

Highlights

- ✓ Successful completion of verification and validation of the 2nd generation ColoSTAT® assay Beta kits confirming required performance for commercial application.
- ✓ ColoSTAT® kit configuration is now optimised for routine lab use with significant improvements in turnaround times.
- ✓ ColoSTAT® Beta kit is transitioning to the final stage of manufacturing by our development and OEM partner, Quansys.

Melbourne, Australia, 26 May 2025: Rhythm Biosciences Ltd ('RHY', the 'Company' or the 'Group') (ASX:RHY), a transformative, predictive cancer diagnostics technology company, is pleased to announce the results from the completion of the ColoSTAT® Beta kit verification and validation. Building on our previous reports on the Alpha kit, these new findings stem from the analysis of our new high-quality, 2nd generation assay kits utilising banked patient samples.

Extensive verification testing was successfully completed by Rhythm and our development partner, Quansys, generating approximately 23,000 data points to evaluate a variety of variables including inter and intraplate precision, interference and detection limits. Pleasingly over 96% of the total tests comfortably met the performance targets for the operational use and the remaining 4% will be compensated for in the final, manufactured product.

Validation of the Beta assay was completed by the Company using banked patient samples and the performance was successfully assessed in two ways:

1. The Beta assay was assessed for analytical variables including precision, reliability and robustness compared to customer needs. The technical performance of the 2nd generation, multiplexed ColoSTAT® assay is substantially improved on all these measures compared to the Alpha kit.
2. It was established that the Beta assay met the performance required to meet or exceed the proposed clinical use as a triage test for patients symptomatic for bowel disease.

Directors

The primary performance objectives of the redesign of the assay into a multiplex format were to:

1. Simplify the completion of the test for a routine laboratory.
2. Reduce turnaround times (TAT).
3. Improve the quality and performance of the assay.
4. Reduce overall cost of goods for the assay.

Following extensive testing the Company has now established a robust and reliable assay with a clearly defined Standard Operating Procedure for running the ColoSTAT® assay, which significantly reduces hands-on time, improves throughput and reduces TAT.

The next step involves the transfer of the Beta kit to production by Quansys to produce Pilot kits, followed by final testing with an independent set of clinical samples. Following completion of the above, Rhythm will be able to make ColoSTAT® commercially available through Rhythm's commercial laboratory following NATA Accreditation or through partner laboratories, utilising their own accreditation.

Rhythm Managing Director and Chief Executive Officer, Dr David Atkins commented *“This is the first time the Company has had a truly stable and reliable, simple to use ColoSTAT® assay with the necessary consistency of demonstrated performance. We are excited to confidently advance to our final testing phase, with commercialisation activities being able to be planned.”*

- ENDS -

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 is curable.

The ColoSTAT® Test-Kit 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. The test is an alternative for individuals who are unable or unwilling to participate in current screening programs. It is being updated to meet relevant regulatory standards.

The ColoSTAT® Test-Kit 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.

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