

## Rhythm Biosciences Maintains ISO 13485:2016 Certification

### Highlights

- ✓ Rhythm retains ISO 13485:2016 certification for its Quality Management System following this second full recertification. Certification has now been held for the last 7 consecutive years.
- ✓ Extension of the scope of the certification now includes the ability to develop hardware as a part of the ColoSTAT<sup>®</sup> system.
- ✓ The successful recertification of the Company's ISO 13485:2016 status ensures an uninterrupted ability to develop high quality In Vitro Diagnostic Devices. This recertification provides clear evidence of Rhythm's commitment to Quality.

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) is pleased to confirm its continued compliance with ISO 13485:2016, the internationally recognised quality management standard for in-vitro diagnostics (IVD) and medical devices. The certification, conducted by the British Standards Institution (BSI), marks the seventh consecutive year Rhythm has successfully achieved and maintained compliance with the standard.

This year's certification also includes an extension to the scope, further strengthening the Company's quality management system. The certification scope now includes design, manufacturing, distribution installation and servicing of in vitro medical devices including immunoassay technology and algorithm software.

Maintaining ISO 13485:2016 certification is a critical component of Rhythm's commercial and market entry strategy. It supports regulatory approvals, enhances market confidence and reinforces the Company's operational credibility. It also validates the robust quality systems Rhythm has established and upheld over an extended period.

Commenting on the ISO certification, Rhythm CEO & Managing Director, Dr David Atkins said: "Rhythm continues to maintain a Quality Management System in line with ISO 13485:2016, supporting both the international launch of ColoSTAT<sup>®</sup> and the Company's ability to supply high-quality raw materials for In-House IVD applications."

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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

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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 collaborating 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<sup>®</sup>**

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<sup>®</sup> 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<sup>®</sup> 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<sup>™</sup>**

geneType<sup>™</sup> 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).