

Market Update - All End of CY'24 Milestones Attained

Highlights

- ✓ Receipt of RDTI returns – Achieved.
- ✓ Delivery of 2nd Generation ColoSTAT® *Beta* Release candidate Multiplex Kits – Achieved.
- ✓ Market-Entry Roadmap for ColoSTAT® Assay – Completed.

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) advises it has attained the CY'24 Milestones outlined in its announcement released to the ASX on 24 October 2024.

Core Product Update - ColoSTAT® *Beta* Release Candidate

Rhythm has received the first batch of the *Beta release candidate* version of the multiplex antibody detection kits developed and manufactured by the Company's CMO, Quansys Biosciences (Quansys), in the USA. These kits are advanced prototypes of the final kit intended for the detection of colorectal cancer using patient blood samples. This achievement is on track with the milestone schedule communicated on 24th October 2024 and sets the stage for further testing and clinical validation of the next-generation colorectal cancer diagnostic ahead of its planned commercial launch in 2H CY'25.

The 2nd generation multiplex assay kits combine five (5) separate antibody-based assays that previously constituted the ColoSTAT® assay into a single reaction for each patient blood sample. The new format was designed in partnership with the team at Quansys to leverage its proprietary technology to further increase the assay's ease of use and reliability for end-user laboratories.

Commercialisation and Regulatory Affairs

The Company is confident the improved assay will meet customer requirements including:

- ✓ reduced assay throughput and turnaround time;
- ✓ Improved reliability; and
- ✓ a reduction in the overall cost of goods of the test.

Company customer insights have identified these three (3) performance parameters as being essential to support commercial adoption of Rhythm's novel clinical assay. "This milestone is a major leap forward, bringing us closer to end-user clinical evaluation and commercialisation," said Nir Dvorski, Chief Operations Officer of Rhythm.

As a result of the outstanding progress being made with the 2nd generation assay, the Company has engaged experienced Clinical, Quality and Regulatory consultants in Australia, UK and the US to assist in finalising the most appropriate path to market in those three priority geographies.

While the ultimate goal for ColoSTAT® is to secure marketing approval by relevant regulatory agencies in each market (e.g., MHRA in the UK, the FDA in the USA and TGA in Australia), an intermediate and more immediate path to market commercialisation is offered by the regulatory paths available to *in vitro* diagnostic medical device (IVD) manufacturers including In House IVD and its equivalents in key geographies. As such, the Company is positively progressing discussions with laboratory partners and is aiming to progress to a commercial roll-out phase in 2H CY'25.

Corporate

The Company successfully took receipt of \$3.23m of its Research & Development Tax Incentive (RDTI), as announced to the ASX on 7 November 2024.

On 19 November 2024, Rhythm announced strong demand for a \$3.5m placement of new shares at \$0.10 per share, with several new institutional, professional, and sophisticated investors participating.

Finally, to ensure the Company can deploy capital on strategically important activities, the Company has outsourced various services including the appointment of Acclime Corporate Services Australia Pty Ltd (**Acclime**) as Company Secretary of RHY effective 6 January 2025. For the purposes of ASX Listing Rule 12.6, Mark Licciardo at Acclime will be the person responsible for communications with the ASX in relation to ASX Listing Rule matters from that date onward. The Board wishes to thank the outgoing Joint Company Secretaries, Mr. James Barrie and Ms. Andrea Steele. Ms. Steele will continue in her role as General Counsel of RHY.

- ENDS -

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

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

David Atkins, PhD Managing Director Chief Executive Officer	Andrea Steele Joint Company Secretary & General Counsel
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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.