

Strategy & Market Update

Rhythm Biosciences Ltd (ASX: **RHY**) (“**Rhythm**” or the “**Company**”) advises that it has completed an in-depth strategic review across the entire business following several executive management changes since April 2023 and as foreshadowed at the 2023 AGM.

In response to significant regulatory changes in Europe and proposed changes in Australia and the USA the Board has resolved to realign its operations and resources to best realise the Company’s objectives and to adopt the new stringent IVDR (In Vitro Diagnostic Medical Device Regulation) requirements for all products in development. As a result of the strategic review there has been an organisational restructure, a significant cost reduction process and the engagement of additional external expertise to assist the team.

Key decisions as a result of the strategic review include:

1. The proposed appointment of a suitably qualified Chief Executive Officer to support the IVDR transition work. As disclosed previously, following a handover period, current Executive Chairman, Mr. Otto Buttula, will relinquish his executive duties.
2. The currently produced ColoSTAT® kits will be used for Research Use Only (RUO) rather than for commercial sales. As a result, the Company’s existing IVDD ColoSTAT® kits will not be made available for commercial sales and therefore the Company does not anticipate any material revenue from its existing IVDD ColoSTAT® kits. Future revenue will be dependent on completion of the proposed IVDR transition work and then obtaining regulatory approvals for the new IVDR compliant kits.
3. A commitment to produce ColoSTAT® to the new IVDR standards which replaces the Company’s current IVDD product approvals (CE & CA Mark and Medsafe). The Company will continue to evaluate options in the US market given FDA regulatory uncertainty.
4. The engagement of a US based Contract Manufacturing Organisation (CMO) to undertake all future design and development work on ColoSTAT®. The decision to engage with a CMO should mean that ColoSTAT® is a more cost-effective product with the benefit of automation. This decision is designed to be able to re-register ColoSTAT® to the new CE & CA Mark (IVDR), Medsafe and TGA standards. The IVDR transition work is the Company’s highest priority for CY24.
5. Significant cost reduction progress has already been achieved with further savings expected to be realised as the cost base is realigned to the new strategic direction.
6. Follow on benefits are expected as the IVDR transition work can be applied to the Company’s technology pipeline including in breast, lung and gastric cancer as previously announced.

The R&D tax incentive (RDTI) is being reviewed following the receipt of Tranche 1 of \$1.69m as announced on 14 November 2023. The Company is planning to re-lodge its RDTI claim for its international component of R&D given the current kits can be used for R&D, however the quantum expected to be received will be materially lower than previously announced.

The Board notes the receipt of a previously disclosed notice under s249D and reiterates its unanimous support for Mr. Otto Buttula with all Director shareholders intending to vote their shares against the resolution.

Rhythm Biosciences Ltd
ACN 619 459 335
ASX: RHY

www.rhythmbio.com

Australian Registered Address
Bio21 Molecular Science & Biotechnology Institute
30 Flemington Road
Parkville VIC 3010 Australia

T +61 3 8256 2880
E info@rhythmbio.com

Directors
Otto Buttula
Sue MacLeman
Trevor Lockett
Rachel David
Louis Panaccio

Executive Chairman
Independent Deputy Chair
Non-Executive Director
Non-Executive Director
Non-Executive Director

- ENDS -

Authorisation & Additional Information

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

For further information contact us via investor@rhythmbio.com or on +61 3 8256 2880:

Mr. Otto Buttula Executive Chairman	Ms. Andrea Steele General Counsel & Company Secretary
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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 Twitter.

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 test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood presence of CRC. The test can be used as an alternative for individuals who are unable or unwilling to participate in current screening programs.

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.