

# **Product and Market Update**

# Phase 2 Milestone: Delivery of New Colorectal Cancer Multiplex Assay Alpha Kit

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) advises it has received the first batch of the *Alpha* version of the multiplex antibody detection kits developed and manufactured by the Company's CMO, Quansys Biosciences (Quansys), in the USA. These kits are functional prototypes of the final kit intended for the detection of colorectal cancer using patient blood samples.

This represents a major step forward for the Company and paves the way for further in-house assay testing in advance of final design iteration and clinical validation of this next generation colorectal cancer diagnostic prior to its planned commercial launch.

The multiplex assay kits combine five (5) separate antibody-based assays that previously constituted the ColoSTAT<sup>®</sup> assay into a single reaction for each patient blood sample. The new format was designed in partnership with the team at Quansys to leverage their proprietary technology to further increase the assay's reliability. Furthermore, the expectation is that the improved assay will address customer requirements in the form of (a) reduced turnaround time, (b) increased assay throughput and (c) 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 a novel clinical assay.

The initial Alpha test results for the multiplex assay have met critical design inputs required at this development stage and pleasingly, the outcome "has exceeded my initial expectations" according to Dr David Atkins, CEO of Rhythm. Dr. Kyle Berg, the R&D Manager leading the project at Quansys, noted, "The assay design has been complex, and reaching this point with these results highlights the expertise and dedication of the Quansys R&D team, the critical antibody selection work by Rhythm, and the strength of our collaborative efforts along the way."

As foreshadowed in our presentation at BioShares Biotech Summit in July of this year, the Company continues to pursue the end-goal of launching a novel, blood-based general colorectal cancer screening assay and to this end, has been exploring opportunities to bring the new assay to market by investigating and targeting clinical applications that represent intermediate steps to this ultimate goal.

As previously communicated, Rhythm will continue to focus on colonoscopy triage in which the Company's multiplex assay will be used to prioritise those individuals scheduled for colonoscopy.

Rhythm Biosciences Ltd ACN 619 459 335 ASX: RHY

Australian Registered Address Bio21 Molecular Science & Biotechnology Institute 30 Flemington Road Parkville VIC 3010 Australia Directors Otto Buttula Sue MacLeman Trevor Lockett Louis Panaccio

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

www.rhythmbio.com

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



Relevant customer input is currently being collected and will be used to prepare final design inputs for these near-term opportunities in key target geographies.

Finally, the Company is in the process of engaging highly experienced consultants to help revise and re-design the regulatory strategy that supports a more appropriate path to market.

As this work on the revised regulatory strategy and commercial plan is completed the Company will make relevant announcements to the market as it relates to its revised strategy.

## - ENDS -

## Authorised for release by the Board.

## For further information contact us via investor@rhythmbio.com:

Dr. David Atkins	Mr. Guy Carisbrooke
Chief Executive Officer	Financial Controller

#### **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<sup>®</sup> 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<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.