

## Rhythm Continues Platform Expansion Program for Other Cancers

### Highlights

- ✓ Rhythm appoints the Baker Institute as second bioanalytical partner to advance the development program for platform expansion into additional cancers;
- ✓ Partnership follows the recent engagement of Agilex Biolabs; and
- ✓ The appointments cover two of Rhythm's largest cancer market opportunities identified outside of near-term entry into colorectal cancer.

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (**Rhythm** or the **Company**) announces further progress with respect to its platform technology expansion program into other cancer markets.

### Market Ready – Initial Colorectal Cancer Markets

Rhythm is focused on developing simple, affordable and highly accurate blood tests for the detection of cancer for global mass-market screening. The Company's initial product, ColoSTAT<sup>®</sup>, is targeting colorectal cancer and is currently market-ready following the successful completion of clinical trials where it was proven to be 35% more accurate in detecting cancer than the current market standard faecal test<sup>1</sup>. ColoSTAT<sup>®</sup> is expected to be launched in Australia in FY'23 (upon Therapeutic Goods Administration (TGA) approval), where the Company is ultimately focused on a growing global addressable market. Rhythm remains confident of TGA approval in the near term and will provide further updates as appropriate.

The Australian market alone represents over 7 million people, over the age of 50, that are eligible for colorectal cancer screening. This number is expected to rise, with evidence from the U.S. Preventative Services Task Force, that the screening age for this cancer be lowered to 45 years. This would define a global addressable 45–74-year population to circa 1 billion people<sup>2</sup>. Further, in a study conducted in the U.S., 93.5% of people preferred<sup>3</sup> to take a blood test over a faecal test when presented with the option. The market outlook for Rhythm's simple cancer detection blood test remains very positive in this context. This is being validated by potential licensing parties that Rhythm is in discussion with, in various global jurisdictions.

### Platform Expansion Program

The Company has identified a number of other markets where it can leverage its validated cancer diagnostics technology platform<sup>4</sup> and commenced a feasibility program earlier in the year. In July 2022, Rhythm announced its first bioanalytical partner, Agilex Biolabs (owned by Healius Ltd (ASX: HLS)), who were engaged to support the development of the first cancer program.

Rhythm has further progressed its feasibility program now confirming a second bioanalytical partner, the Baker Institute, who have been engaged to advance proof of concept for a second cancer program. The

<sup>1</sup> See ASX Announcement 4 April 2022

<sup>2</sup> RHY estimates, potential screening market based on population over 45 years old in the United States, Europe, China, Japan, and Australia

<sup>3</sup> Loannou S, Sutherland K, Sussman DA, Deshpande AR. Increasing uptake of colon cancer screening in a medically underserved population with the addition of blood-based testing. BMC Cancer. 2021 Aug 28;21(1):966

<sup>4</sup> See ASX Announcement 14 December 2021

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Rachel David	Non-Executive Director
Louis Panaccio	Non-Executive Director

Baker Institute is an independent, internationally renowned medical research facility, with a history spanning more than 96 years, focusing on diagnosis, prevention and treatment of diabetes, cardiovascular disease and associated metabolic diseases. The Company's will focus on feasibility, testing and validation of the biomarkers of interest identified by Rhythm.

**Commenting on the Platform Extension progress, Rhythm CEO and Managing Director, Glenn Gilbert, said:**

*"The Company is in a great position being on the cusp of initial market entry for its colorectal cancer blood test, and in parallel assessing options on how to leverage the technology platform into other cancers.*

*Attracting two well-known bioanalytical partners to work with Rhythm on platform extension supports our scale ambitions and is designed to provide optional market opportunities to explore while we focus in the near term on deploying our cancer detection technology into unfortunately, growing colorectal cancer screening markets."*

**- ENDS -**

**Authorised for release by the Board.**

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## About Baker Institute

The Baker Heart and Diabetes Institute (Baker Institute) is an independent, internationally renowned medical research facility, with a history spanning more than 96 years. The Institute's work extends from the laboratory to wide-scale community studies with a focus on diagnosis, prevention and treatment of diabetes, cardiovascular disease and associated metabolic diseases. The Institute's mission is to reduce death and disability from cardiovascular disease, diabetes and related disorders; two prevalent and complex diseases responsible for the most deaths and the highest health costs in the world.

## About Rhythm Biosciences

Rhythm Biosciences is focused on becoming a globally significant, transformative, predictive diagnostics company, specialising in cancer detection technology. The Company is currently developing ColoSTAT<sup>®</sup> - a simple, low-cost, blood test for global mass market detection of colorectal cancer.

Worldwide, colorectal cancer is the third most common cancer in men and the second most common in women, accounting for an estimated 1.9 million new cases and 935,000 deaths annually.

In an effort to reduce the global burden, many countries have implemented screening programs aimed at early detection. These programs are predominantly administered with a faecal immunochemical test (FIT) for the assessment of colorectal cancer risk, with a positive result referred for a colonoscopy. FIT only analyses the presence of blood in faeces, which can occur for several reasons other than cancer, therefore it is not designed as an accurate test for cancer. Many people simply don't take the test for fear of an unnecessary colonoscopy procedure, unpleasantness, difficulty, or for religious/cultural reasons. There is currently no appropriate blood test alternative.

Rhythm aims to transform the global mass-market for colorectal cancer detection with ColoSTAT<sup>®</sup> its simple, low-cost blood test that is fit for purpose, meaning that it is designed to actually detect colorectal cancer. Since listing on the ASX in 2017, the Company has run a successful multi-year research and development program that has delivered technical validation of the core biomarker technology, being reproducible and stable. The ColoSTAT<sup>®</sup> test-kit was manufactured in 2021 and delivered performance testing that outperforms the current market standard faecal immunochemical test utilising Rhythm's proprietary algorithm. The Company is progressing regulatory, manufacturing and scale up activities ahead of market entry in FY23.

ColoSTAT<sup>®</sup> is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT<sup>®</sup> has the potential to play a key role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Rhythm's initial targeted global addressable population is over 800 million people which are over 50 years of age. Almost 70%, or 550 million people, are not currently screened for colorectal cancer due to the limitations of the current faecal based testing regime. This "at risk" population is also expanding with the disease growing rapidly in much younger age groups. Early detection and intervention can lead to cure in over 90 per cent of new cases, therefore the need for effective screening and early intervention has the potential to save a significant number of lives. Rhythm estimates today's colorectal cancer screening market alone to be worth in excess of \$38 billion.