

## Rhythm Advances Platform Expansion Program with Other Cancers

### Highlights

- ✓ Rhythm completes initial biomarker review to support platform expansion of its core cancer detection technology;
- ✓ Leading biomarkers have been identified that are critical to progress research and development into each other target cancers: Breast, Lung, Cervical, Pancreatic and Gastric;
- ✓ Feasibility phase commenced, with first bioanalytical partner, Agilex Biolabs, engaged to accelerate development program; and
- ✓ Focus remains on preparations for market launch of ColoSTAT<sup>®</sup> before the end of CY'22.

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (Rhythm or the Company) is pleased to announce positive progress with respect to its platform technology expansion program.

### Background

A key focus within the Company's Strategic Plan is to identify opportunities to leverage the core cancer detection capabilities within a platform expansion program. The key lead biomarker for Rhythm's initial bowel cancer product, ColoSTAT<sup>®</sup>, provides a strong catalyst to progress new activities for the early detection of a range of other cancers ("pan-cancerous" attributes).

### Platform Expansion – Targeting Five Additional Cancers

Following Rhythm's announcement that it would target five (5) additional cancer diagnostics (refer ASX Announcement 14 December 2021), the Company formally commenced a research and development program earlier this year that included a detailed and robust biomarker review. The review included sophisticated analysis of thousands of biomarkers with the outcome resulting in Rhythm having identified leading biomarkers for each of the outline target cancers: Breast, Lung, Cervical, Pancreatic and Gastric. Some of the biomarkers identified appear to be common between cancer types.

With the first phase of the expansion program complete, Rhythm is now focused on accelerating the next stage of feasibility, testing and validation of the biomarkers of interest. To progress these activities appropriately and enable the team to continue to focus upon ColoSTAT<sup>®</sup>, the Company has engaged the services of Agilex Biolabs ("Agilex") under an agreement to support feasibility, validation and development works associated with the platform technology expansion program for one initial cancer target. Agilex is Australia's largest and most technologically advanced bioanalytical and toxicology laboratory with 25 years' experience providing a comprehensive suite of bioanalytical services to biotech and pharmaceutical companies - with a particular focus and expertise in oncology. They were acquired earlier this year by Australian healthcare and pathology company Healius Limited (ASX: HLS) which further supports Rhythm's desire to partner with best-in-class operators within the healthcare sector.

#### Directors

**Rhythm CEO and Managing Director, Glenn Gilbert, commented:**

*“The completion of the initial program of biomarker identification directly supports our platform expansion program and is a significant step forward.*

*The potential here is exciting across the five additional cancer targets that have unmet screening needs and globally addressable markets. The Company is working diligently to consider how best to leverage the outstanding cancer detection technology already built for ColoSTAT<sup>®</sup>.”*

**- ENDS -**

**Authorised for release by the Board.**

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## About Agilex Biolabs

Agilex is one of Australia's leading bioanalytical laboratories, with over 25 years in the industry delivering broad bioanalytical capabilities and therapeutic experience to biotech and pharma clients. Agilex has a reputation for quality with internationally recognised certifications, employing over 180 scientific professionals with laboratories in Adelaide and Brisbane servicing customers in over 10 countries across Asia, Europe, and the USA.

## 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® - 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® 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® 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 currently finalising its clinical trial for ColoSTAT®, and is progressing regulatory, manufacturing and scale up activities ahead of market entry in 2022.

ColoSTAT® is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT® 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.