ASX Announcement

# RHYTHM BIOSCIENCES

## Rhythm Targets 5 Additional Cancer Diagnostics For Platform Technology Expansion

- Rhythm identifies five new cancer detection markets to expand its platform technology;
- Development program commenced to validate a commercial pathway; and
- ✓ Primary focus remains on launching initial bowel cancer product ColoSTAT<sup>®</sup> in CY2022.

**14 December 2021, Melbourne:** Transformative 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 strategy.

## CORE TECHNOLOGY

As part of the Company's FY'22 Strategic Plan, a key focus has been to identify opportunities to leverage the core cancer detection technology within a platform expansion program. The key lead biomarker for Rhythm's initial bowel cancer product, ColoSTAT<sup>®</sup>, is believed to possess multi-cancer detection properties that could provide a foundation for platform technology expansion. Having already been internally developed, optimised, validated and granted a CE Mark, this lead biomarker provides a strong catalyst to progress new activities for the early detection of a range of other cancers.

## PLATFORM EXPANSION

Rhythm has now identified a number of additional cancer target markets that will form part of a Research and Development program that should ultimately follow a similar commercial pathway to ColoSTAT<sup>®</sup>. The Company believes it could add meaningful value in these segments to transform both screening and detection for improved health outcomes on a global scale.

Updates will be provided in due course relative to the assessment progress and indicative timelines. The initial five additional cancers to be targeted include:

- Breast;
- Cervical;
- Lung;
- Gastric; and
- Pancreatic.

This platform expansion development program is funded to \$0.75m, as outlined in use of funds statement at the Company's last capital raising. Moreover, the R&D work conducted will also be eligible for the Government R&D tax incentive rebate and potentially other associated grants.

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

"As we move closer to the launch of our initial cancer detection product ColoSTAT® in 2022, the Company is making positive progress with respect to its broader strategy to leverage our cancer detection technology into other global cancer markets. Ultimately, Rhythm believes it can make a meaningful impact for improved health outcomes across millions of people around the world."

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## FOCUS REMAINS ON COLOSTAT® COMMERCIALISATION

Despite the commencement of the platform expansion program, led by Technical Director, Dr Trevor Lockett, in conjunction with an international based analytics company, the Company's immediate focus remains on ColoSTAT<sup>®</sup>, with concentration being on regulatory and commercialisation activities. Having been successfully granted a CE Mark (released 30 November 2021), the Company is considering earlier applications for regulatory approvals in other jurisdictions and is in several discussions in relation to regional commercialisation opportunities.

### - ENDS -

### Authorised for release by the Board.

For further information contact:

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### **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 (FIT) utilising Rhythm's proprietary algorithm. The Company is currently finalising its clinical trial for ColoSTAT<sup>®</sup>, and is progressing regulatory, manufacturing and scale up activities ahead of market entry in 2022.

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.