

Market Update

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) is pleased to announce a market update of current activities in the interest of full and ongoing transparency to all shareholders. An out-of-cycle update has been prepared given recent volatile trading in the Company's securities, in addition to the next formal reporting not being due until the end of January 2023, barring the successful conclusion of various price sensitive activities.

Therapeutic Goods Administration (TGA)

On 12 May 2022, the Company filed its complete submission with the TGA for the listing of ColoSTAT® on the Australian Register of Therapeutic Goods (ARTG). The TGA has acknowledged it is assessing the filing, with no further formal correspondence being received.

The Company acknowledges that the review process has taken longer than initially envisaged when filed but notes that, due to Covid-19 and a backlog in medical device assessments, the median review period of the TGA has lengthened, particularly in regard to new medical devices.

The Company remains confident in the validity of its filing and will update the market accordingly as further substantive progress is made.

Commercial Activities

AUSTRALIA – The Company remains in ongoing discussions with multiple potential major partners, and also in direct communication with State and Federal government officials. Whilst these discussions are at various levels of advancement, the Company believes listing on the ARTG will lead to finalising the best commercial outcome for shareholders.

NEW ZEALAND – As announced to the ASX on 3 November 2022, Rhythm has completed the regulatory process and achieved authorisation as a manufacturer for ColoSTAT®. This means Rhythm can market ColoSTAT® for sale, progress pre-sales activities and further accelerate commercial activities. Multiple partnering discussions are underway and expected to be concluded before the end of FY'23.

ASIAN REGION – Rhythm is in ongoing dialogue with several companies across the Asian region. Particular partners have regional capacity, whilst some more tailored and country specific priorities. Pricing and manufacturing capacity is particularly important in this region, with Rhythm paying close attention to the companies that have strong payer and Government relationships.

EUROPE – Rhythm is in dialogue with a variety of companies, of differing sizes in various countries within Europe, all of which have differentiated risk appetites. Discussions remain ongoing and are at various levels of advancement. Similar to Asia, some potential partners would prefer regional style deals, whereas others may be country specific. Rhythm is in the fortunate position of having a unique test, that has a significant unmet need and strong demand.

U.S.A. – The Company has had discussions with several major potential CLIA laboratory partners and intends to expedite market entry during the course of CY'23 via the Lab Developed Test (LDT) pathway in the first instance.

Across all geographies, Rhythm are intentionally being selective as to who we partner with. Additionally, we will only appoint distributors/partners on commercially favourable terms that will deliver solid medium to long term growth and profitability. Further, the positive feedback that Rhythm have received confirms the need for additional manufacturing capability to ensure global demand can be met.

Platform Expansion – 2nd additional cancer target commenced

In an ASX announcement dated 14 December 2021, Rhythm stated that the key lead biomarker for its initial bowel cancer screening product, ColoSTAT[®], is believed to possess multi-cancer detection properties and provided a strong catalyst to progress a platform of diagnostic blood tests for the early detection of a range of other cancers.

Other targeted cancers include:

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

1st Additional Cancer Target: As announced to the ASX on 19 July 2022, following a contracted third-party review which included sophisticated analysis of thousands of biomarkers and given the Company's desire to keep its team focussed on ColoSTAT[®], the Company contracted Agilex Biolabs ("Agilex"), a Healius Ltd (ASX: HLS) subsidiary, to conduct feasibility, validation and development works for an initial cancer target.

2nd Additional Cancer Target: As announced to the ASX on 15 December 2022 and continuing the Company's desire to keep its team focussed on ColoSTAT[®], the Company is pleased to announce that it has now entered into a contract with the Baker Institute to conduct feasibility, validation and development works for a second additional cancer target. Commensurate with this announcement we can confirm that works have now commenced.

Expansion of Manufacturing

Further to our established third-party manufacturer, the France based Biotem, market feedback regarding demand in various countries has led us to focus on additional manufacturing capability, in additional geographies.

Rhythm is engaging a U.S based manufacturing company to support market entry into that country. It is foreseen that this manufacturer will have capacity to support Biotem in global supply. As such, the associated feasibility and scale up of commercial manufacturing works are advancing ahead of planned production runs of commercial ColoSTAT[®] test-kits in early to mid CY'23.

The Company will also examine the feasibility of manufacturing domestically.

Health Economics / Cost Benefit

The Company has commissioned a global third party, Clarivate, to conduct health economic/cost benefit modelling to further support marketing efforts and the next stages of commercialisation, including reimbursement.

The body of work will generate an interactive model that can be tailored for Government, Private Health Insurers and other payors alike. The Company will have more to report on the results in due course, but can indicate that the initial results are conclusively positive, with patients preferring a blood based test, hence increasing screening compliance, hence saving lives and delivering significant cost savings to insurers and governments alike.

Rhythm CEO and Managing Director, Glenn Gilbert, commented:

“We acknowledge shareholder sentiment with respect to the Australian opportunity which is currently pending TGA review. The Company remains confident that it has provided a strong filing to obtain approval and whilst unable to provide a timeframe, as it is not within our control, Rhythm continues to progress pre-market entry activities. The technical validation of ColoSTAT® and outstanding clinical trial results speak for themselves.

More importantly, we expect our current and future products to be able to save lives, via more efficient screening.

We are further encouraged by positive feedback from potential partners that the global demand for a simple blood test for cancer detection is significant. The Company is well positioned to maximise commercial outcomes and deliver ongoing, significant shareholder value.”

- ENDS -

Authorised for release by the Board.

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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® - 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 progressing regulatory, manufacturing and scale up activities ahead of market entry in FY23.

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.