

FY'22 Strategic Update

- **Strategic planning process concluded to advance global commercialisation activities for ColoSTAT[®];**
- **Rhythm to fast-track priority market entry strategy, platform technology expansion and regulatory processes; and**
- **Target first revenue late 2022.**

18 May 2021, Melbourne: Rhythm Biosciences (ASX: RHY) is pleased to confirm progress on a number of activities related to the commercialisation of its cancer detection technology, ColoSTAT[®].

The Company's FY'22 strategic plan has resulted in a number of outcomes designed to advance commercial activities to support its path to market. These included:

USA Market Entry – Accelerate

- ✓ Incorporate a 100% owned USA domiciled entity;
- ✓ Appoint appropriate Board, inclusive of USA based Directors;
- ✓ Target approved Clinical Laboratory Improvement Amendments (CLIA) laboratory via a lab developed test (LDT), appropriate for ColoSTAT[®]; and
- ✓ Commence initial stages of FDA approval pathway, ultimately leading to FDA clearance or approval.

Platform Technology Expansion - Commence

- ✓ Confirm initial data that Rhythm's key lead biomarker has global application and is highly expressed in a range of cancers;
- ✓ Set up a separate corporate entity in Australia for the technology to reside within;
- ✓ Complements our simple, low cost, mass market cancer diagnostics strategy;
- ✓ Not expected to be capital intensive, existing biomarker tests have already been validated and established; and
- ✓ Creates opportunity for collaboration and non-dilutive grants.

Regulatory entry for Europe (CE Mark) and Australia (TGA) - Confirmation

- ✓ Confirmed approach to submit for CE Mark approval in advance of Study 7 completion and TGA (Australia) regulatory filing;
- ✓ CE Mark filing expected to be late 2021;
- ✓ CE Mark filing contingent of receipt and confirmatory testing of next batch of test-kits received from Biotem;
- ✓ Commence engagement with TGA regarding regulatory filing in Australia;

- ✓ Confirmation on recruitment completion and expected submission dates to be provided in further market updates;
- ✓ Recruitment for Study 7 continues to accelerate with final expected numbers required to be confirmed. There is scope to reduce the expected broader 1,000 patients that the Company are being confirmed with the TGA;
- ✓ All patients recruited in the trial continue to provide a faecal test, a colonoscopy and a blood draw - to be tested at the end of the recruitment period, with the most updated and appropriate ColoSTAT® test-kit and algorithm; and
- ✓ Rhythm continues to collect the data for the faecal testing and the colonoscopies undertaken to date.

Reiterating that the current ColoSTAT® test-kit has demonstrated exceptional, repeatable, and robust analytical performance results in both in Study 6 (16 March 2021) and the more recent Lifestyle Related Factors (LRF) study (6 May 2021).

Business Development - Accelerate

- ✓ Initiate business development activities relating to the most beneficial and appropriate market entry strategies into Europe, Australia, New Zealand, China and broader Asian countries; and
- ✓ The Company will be updating the market in the coming months in this regard.

Rhythm CEO, Glenn Gilbert, commented:

“Following the exceptional ColoSTAT® performance results from Study 6 and the LRF algorithm enhancement work, this has given the Company confidence to now accelerate the execution of our commercial strategy, focusing on our path to market activities.

ColoSTAT® will transform the global mass-market cancer diagnostic market, with exciting and positive impacts at a social and economic level.”

Timelines and updates for the above are expected to be communicated as the respective programs are advanced and will be reported in future periodic updates.

With authority by the Board.

For further information, please contact:

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About Rhythm Biosciences

Rhythm Biosciences (ASX: RHY) is a transformative, predictive diagnostics company, specialising in early cancer detection. Rhythm's initial business pursuit is centred upon technology originally developed by the CSIRO and involves the development and commercialisation of a screening and diagnostic test for the early detection of colorectal cancer, the third biggest cause of cancer-related deaths globally.

Rhythm's lead product, ColoSTAT[®], is intended to be a simple, affordable, minimally invasive and effective blood test for the early detection of bowel cancer for the global mass market. It is expected to be comparable to, if not better than, the current standard of care, the faecal immunochemical test (FIT), at a lower cost. ColoSTAT[®] also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

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 an important role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Globally, over 850,000 people die from colorectal cancer each year. Colorectal cancer is typically diagnosed at a later stage when there is a poor prognosis for long-term survival. Annual estimated unscreened 50-74-year old's is estimated at +130m for the US, EU and AU alone, with this market potential being more than \$6.5b.