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**ASX Announcement**
ASX code: RHY
ACN: 619 459 335

# Rhythm Biosciences Quarterly Report - September 2020

## Quarter Highlights:

- ✓ **Successful technical validation of final four adjunct biomarkers for ColoSTAT®, significantly reducing core technology development risk;**
- ✓ **Three additional Clinical Trial sites appointed and recruiting;**
- ✓ **Commencement of technology transfer to high volume manufacturer;**
- ✓ **Prototype ColoSTAT® test-kit being finalised;**
- ✓ **Successful completion of approximately $6 million Capital Raising, with majority of new shares acquired by existing shareholders via a 3 for 5 Rights Issue; and**
- ✓ **$6.17 million of cash on hand, at 30 September 2020.**

## Subsequent to period-end:

- **Receipt of $1.1 million Research and Development Tax Refund; and**
- **Northern Beaches Clinical Research added to Study 7 (Clinical Trial) as seventh trial site.**

**29 October 2020, Melbourne:** For the quarter ended 30 September 2020, transformative medical diagnostics company Rhythm Biosciences Ltd (ASX: RHY) continued the development of its ColoSTAT® test-kit which is expected to be commercialised as a globally marketed, low-cost, simple blood test for the detection of colorectal cancer, via mass-market screening diagnostic practices.

### Development update

The Rhythm development team has continued to work through the ongoing COVID-19 lockdown in Victoria. Despite the company having experienced some delays in receiving materials and slower than expected Study 7 recruitment, the team have made significant scientific progress.

### Biomarker Development – Successfully Technically Validated

Pleasingly, as envisioned in the previous Quarterly report (released 29 July 2020), Rhythm has successfully technically validated a total of four adjunct biomarkers within the estimated timeframe of Q1FY'21. The adjunct biomarkers are expected to support the key lead biomarker (total of 5 biomarkers) as part of the overall ColoSTAT® test-kit.

This is a significant step for the Company and continues to de-risk the technology from a scientific perspective.

ColoSTAT® will predominantly use its own version of antibodies which are intended to be combined in the final test-kit. This will enable Rhythm to maintain and generate new intellectual property, potentially improving the performance of the test and providing greater control over the quality, supply and cost of materials.

With the underpinning antibody technologies now technically validated, the Company is focused on completing the next phase in the development program which includes refining the ColoSTAT® test-kit algorithm via further analytical cancerous and healthy blood sample testing, transferring the core technology to a high volume manufacturer and completing a further battery of tests relating to the ColoSTAT® test-kit verification, required for regulatory purposes.

Importantly, the cancerous and healthy sample testing indicated above will lead to the completion of the initial prototype test-kit, including determination of the final biomarker panel.

**Clinical Trial – Additional Trial Sites Signed and Recruiting / Reviewing Further Sites**

Rhythm has successfully appointed three additional Clinical Trial sites during the quarter. All new sites are based in New South Wales, in line with Rhythm's commitment to appoint sites outside of Victoria. Impressively, these sites have all commenced recruiting patients. Both Rhythm and the Clinical Research Organisation (CRO) are working closely with these sites to ensure that early recruitment rates are sustained and accelerating.

Unfortunately, clinical trial recruitment remains paused in Victoria. The major reason being the clinical trials staff at those large public hospitals are not, as yet, back to 'typical' clinical trial work with staff currently deployed to other hospital departments. As previously communicated, these clinical trial staff members are required to identify potential patients, complete the patient consent forms, document medical histories to determine if that patient is suitable for the clinical trial, along with completing other associated documentation. We continue to maintain regular contact with the sites and will advise when the Victorian sites recommence recruitment.

Having delivered on our previous promise to appoint trial sites during 1QFY'21, we similarly anticipate appointing new, additional sites in 2QFY'21 (subject to the individual hospitals / sites internal governance and approval processes).

Currently, the Company is unable to provide a specific and updated timetable for regulatory submissions, particularly that to the TGA that requires the clinical trial (Study 7) to be completed.

At the time of writing, despite some material uncertainties, the recent appointment of additional trial sites and further potential sites strategically identified, it is expected that patient recruitment will be completed during calendar 2021, subject to no significant further COVID-19 outbreaks and unforeseen delays.

Rhythm and its analytical testing partner, Sonic Clinical Trials, have a strong relationship and are aligned to complete the ColoSTAT® testing as soon as practicable following the completion of patient recruitment.

**Regulatory – Ongoing Review of EU Pathway**

The Company may apply for a CE Mark in advance of the completion of the final clinical trial (Study 7) report. This will be guided by appropriate, satisfactory, and robust data availability from Study 6 and our ongoing verification testing program.

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**Successful antibody and algorithm development**

Having successfully completed the technical validation of predominantly its own version of antibodies which are expected to be combined within the final ColoSTAT® test, the R&D focus now turns to further testing on numerous cancerous and healthy blood samples and finalising the initial prototype test-kit. This testing is designed to refine Rhythm's proprietary algorithm to achieve required sensitivity and specificity performance. This is a key step to completing Study 6 testing activities (expected to be completed by 3Q'FY'21). We anticipate our algorithm will have the capability to continue to 'learn' and be trained on future data sets that may potentially deliver further performance improvements. Successful progression of internal testing relating to Study 6 is expected to further de-risk the technology.

The global unmet need and market opportunity for Rhythm's ColoSTAT® test kit has not diminished despite the current global conditions. The Company remains confident on executing upon its development plan.

**Operations / Corporate – Capital Raise – Successful ~$6m Capital Raise via Placement and Rights Offer**

On 23 July 2020, Rhythm announced it would conduct two Placements and a Non-Renounceable Rights Issue ("Offer") to raise approximately $6.0 million. The Offer subsequently closed on 28 August 2020.

Importantly to management and the Board, the majority of funds was raised from existing shareholders, via a 3 for 5 Rights Issue. The price set of $0.06 per share represented a discount of 23% to the lowest traded price of $0.078, during the price setting period.

The Placements successfully raised approximately $2.4 million before costs, with the Rights Issue raising approximately $3.6 million before costs. Rhythm had received firm commitments from third parties for up to the maximum amount sought of $2.25 million of any shortfall available under the Rights Issue.

A General Meeting of shareholders was held on 25 August 2020 with both resolutions passing. Resolutions related to the issue of:

- 15,112,500 shares pursuant to Listing Rule 7.1 (15% Placement capacity) to sophisticated, professional and other exempt investors, representing circa $0.9 million; and
- 25,000,000 shares to Rhythm Non-Executive Chairman, Mr Otto Buttula (and/or nominees), representing a $1.5 million commitment.

As a result, Mr Buttula has now become a substantial shareholder of the Company. The board and staff now represent 26.82% of the ownership of the company, exhibiting strong alignment with the Company's shareholder base.

**Human Resources – Revised CEO Contract and Employee LTIP**

On 14 September 2020, Rhythm announced it had executed a revised agreement with its CEO. The key revisions related to re-setting of the Short-Term Incentive Plan (STIP) and Long-Term Incentive Plan (LTIP).

Concurrently, the Board approved a LTIP for all Rhythm employees as part of the Company's Employee Share Ownership Plan (ESOP). The plan comprised of long-term options to be allocated to Rhythm employees, aligning their interests with that of shareholders.

**COVID-19 Update – No Material Change to Previous Update**

As per the Company's COVID 19 Update (released 9 April 2020) and subsequent update in the June quarterly (released 29 July 2020), Rhythm is pleased to have been able to maintain its Research & Development staff within the laboratory.

The Company has experienced some delays in the receipt of various materials from international suppliers primarily due to the backlog and re-routing of ports associated with freight processing, particularly in Victoria. Rhythm continues to monitor and plan accordingly to minimise any delays to the development program as has successfully been done to date.

Similarly, delays continue to be experienced within patient recruitment and some blood sample collection for both Study 6 and the clinical trial (Study 7), specifically the Victorian trial sites. With the impact of COVID-19 affecting the development program and Rhythm's partner suppliers, the Company is unable at this time to provide a specific, updated timeframe for the achievement of its key milestones, associated with the clinical trial, CE Mark and TGA regulatory submissions. Rhythm will continue to assess the development schedule and provide updates accordingly.

**Annual General Meeting**

On 16 September 2020, Rhythm announced its Annual General Meeting (AGM) will be held virtually on 18 November 2020 at 11:00am.

The Company would like to take this opportunity to remind shareholders to consider providing their email addresses to the Share Registry, if they have not done so previously, to facilitate shareholder communications. Material announcements will continue to be made via the ASX platform.

**Related Party Payments**

In line with its obligations under ASX Listing Rule 5.3.5, Rhythm Biosciences Limited notes that the only payments to related parties of the Company, as advised in the Appendix 4C for the period ended 30 September 2020, pertain to payments to directors for fees, salary and superannuation.

**Cash on Hand**

Rhythm finished the September 2020 quarter with a cash balance of $6.17 million.

Subsequent to period-end on 16 October 2020, Rhythm announced it received a research and development (R&D) tax refund totaling $1.1 million, as part of the Australian government's R&D tax incentive.

**Future Value Inflection Points**

Matters we expect to deliver upon in the next two quarters include:

- Preliminary specificity and sensitivity results;
- Additional trial site recruitment;
- Prototype test-kit completion;
- Transfer of prototype test-kit to high volume manufacturer; and
- Study 6 completion.

With the authority of the Board.

For further information, please contact:

Glenn Gilbert
Chief Executive Officer
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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.

# Appendix 4C

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

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**Name of entity**

RHYTHM BIOSCIENCES LIMITED

| **ABN** | **Quarter ended ("current quarter")** |
|---|---|
| 59 619 459 335 | 30 SEPTEMBER 2020 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (3 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | | |
| 1.2 | Payments for | | |
| | (a) research and development | (1,176) | (1,176) |
| | (b) product manufacturing and operating costs | | |
| | (c) advertising and marketing | | |
| | (d) leased assets | | |
| | (e) staff costs (not included above) | (131) | (131) |
| | (f) administration and corporate costs | (130) | (130) |
| 1.3 | Dividends received (see note 3) | | |
| 1.4 | Interest received | 8 | 8 |
| 1.5 | Interest and other costs of finance paid | (2) | (2) |
| 1.6 | Income taxes paid | | |
| 1.7 | Government grants and tax incentives | | |
| 1.8 | Other (COVID-19 Government stimulus) | 38 | 38 |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,393)** | **(1,393)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | | |
| | (b) businesses | | |
| | (c) property, plant and equipment | (12) | (12) |
| | (d) investments | | |
| | (e) intellectual property | | |
| | (f) other non-current assets | | |

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| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (3 months) $A'000 |
|---|---|---|---|
| 2.2 | Proceeds from disposal of: | | |
| | (a) entities | | |
| | (b) businesses | | |
| | (c) property, plant and equipment | | |
| | (d) investments | | |
| | (e) intellectual property | | |
| | (f) other non-current assets | | |
| 2.3 | Cash flows from loans to other entities | | |
| 2.4 | Dividends received (see note 3) | | |
| 2.5 | Other (provide details if material) | | |
| **2.6** | **Net cash from / (used in) investing activities** | **(12)** | **(12)** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | 6,034 | 6,034 |
| 3.2 | Proceeds from issue of convertible debt securities | | |
| 3.3 | Proceeds from exercise of options | | |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | (224) | (224) |
| 3.5 | Proceeds from borrowings | | |
| 3.6 | Repayment of borrowings | (34) | (34) |
| 3.7 | Transaction costs related to loans and borrowings | | |
| 3.8 | Dividends paid | | |
| 3.9 | Other (provide details if material) | | |
| **3.10** | **Net cash from / (used in) financing activities** | **5,776** | **5,776** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 1,798 | 1,798 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,393) | (1,393) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (12) | (12) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (3 months) $A'000 |
|---|---|---|---|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | 5,776 | 5,776 |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |
| **4.6** | **Cash and cash equivalents at end of period** | **6,169** | **6,169** |

| 5. | Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | Current quarter $A'000 | Previous quarter $A'000 |
|---|---|---|---|
| 5.1 | Bank balances | 1,669 | 298 |
| 5.2 | Call deposits | 4,500 | 1,500 |
| 5.3 | Bank overdrafts | | |
| 5.4 | Other (provide details) | | |
| **5.5** | **Cash and cash equivalents at end of quarter (should equal item 4.6 above)** | **6,169** | **1,798** |

| 6. | Payments to related parties of the entity and their associates | Current quarter $A'000 |
|---|---|---|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 135 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | - |

Payments in 6.1 relate to Director fees and consulting services.

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

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| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **Total facility amount at quarter end $A'000** | **Amount drawn at quarter end $A'000** |
|---|---|---|---|
| 7.1 | Loan facilities | 27 | 27 |
| 7.2 | Credit standby arrangements | | |
| 7.3 | Other (please specify) | | |
| 7.4 | **Total financing facilities** | 27 | 27 |

| | | |
|---|---|---|
| 7.5 | **Unused financing facilities available at quarter end** | - |

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

The loan facility relates to a rent lease liability recorded under Accounting Standard AASB 16.

| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | (1,393) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 6,169 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 6,169 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 4.43 |

*Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.*

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

*Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.*

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## Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: ....29 October 2020.....

Authorised by: .....
Glenn Gilbert – CEO

(with authority by the Board)

**Notes**

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

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