

## **Rhythm Biosciences Quarterly Report – March 2024**

## **Highlights**

- ✓ Internationally Renowned Clinically Advisory Board Established, with initial meeting held;
- ✓ Initial Phase of Rights Issue closed raising \$2.48m;
- ✓ The current patent review and renewals of ColoSTAT® in preferred markets, will lengthen patent protection by more than a decade to early 2042;
- ✓ Phase 1 outcomes for ColoSTAT® IVDR update, with U.S. based Contract Manufacturing Organisation (CMO), exhibiting positive results; and
- ✓ Board's Unanimous Recommendation supported in Extraordinary General Meeting (EGM).

## Subsequent to Period End

- ✓ Further funding commitments received under open Rights Issue prospectus, with PAC Partners and executives continuing discussions with potential investors;
- ✓ Maintained ISO 13485:2016 Certification; and
- ✓ Appointment of Dr David Atkins as new Chief Executive Officer.

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (Rhythm or the Company) is pleased to provide an update on activities for the quarterly period ended 31 March 2024. This report includes ongoing Company development activities aimed at progressing the commercialisation of ColoSTAT®, Rhythm's simple blood test for the detection of colorectal cancer aimed at global mass market screening, in addition to leveraging the Company's technologies into a range of other cancer diagnostic initiatives.

#### Corporate

Appointment of Dr David Atkins as the Company's new Chief Executive Officer (CEO) - Subsequent to period end and as announced on 24 April 2024, the Board is pleased to confirm the appointment of a new CEO, commencing on 13 May 2024.

Dr Atkins was selected following a comprehensive and competitive search, which considered both experienced and highly credentialled local and international candidates.

Dr David Atkins is an accomplished global healthcare leader with experience across a broad range of life sciences and healthcare disciplines, having gained deep experience in R&D, product development and commercialisation across biotech, medical device, IVD and data-driven solutions across all major international markets. (The Company advises interested shareholders to read the biography provided in its ASX announcement of that date).

ACN 619 459 335 ASX: RHY

Non-Executive Director



Shareholder meetings with the new CEO will be organised post commencement, with Dr Atkins also being invited to present the Company at the 2024 Bioshares Biotech Summit in early July.

**Rights Issue** – The initial phase of the Company's Rights Issue (as announced to the ASX on 9 February 2024) closed on 14 March 2024, raising ~\$2.48m. Subsequent to period end the Company has received further non-material cash commitments upon the same terms as the prospectus and is currently working with PAC Partners Securities Pty Limited (as announced to the ASX on 20 February 2024) and several interested investors to secure further investment in the Company on the same terms as the Rights Issue for entitlements not subscribed for (Shortfall Shares).

Interested parties should contact PAC Partners principal, Sean Kennedy at corporate@pacpartners.com.au.

**Extraordinary General Meeting** – The Board's unanimous recommendation to vote AGAINST the resolution was upheld.

**R&D Tax Incentive (RDTI)** – The Company is concluding deliberations with its Tax Advisers and Auditors in relation to resubmitting a portion of its' R&D Tax Incentive claim for overseas activities, given the reclassification of product inventories to research use only ('RUO'). The outcome of this claim will be advised upon determination, however, works completed as advised by the Company's Tax Advisors suggest a material refund.

**Cost Reduction Strategy** – Costs have continued to be heavily scrutinised and following the completion of final, substantial payments for previous kits ("research-only") manufactured in both Europe and the U.S.A., the Company is confident that future manufacturing costs have fallen substantially and will be evident in future quarters.

**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 31 March 2024, pertain to payments to directors for fees, salary, and superannuation.

#### Manufacturing

**New U.S. based Contract Manufacturing Organisation (CMO) for IVDR submission** – Strong initial progress has been achieved in the redesign and development work of ColoSTAT®, implementing the new IVDR work requirements, with positive results continuing to be exhibited.

#### Phase 1 activities included:

- ✓ the transferring of the technology to a multiplex platform; and
- ✓ improvement of biomarkers and the functionality of the reagents were reconfirmed on the new platform.

#### Phase 2 activities are underway and include:

- ✓ initial assay and reagent refinement; and
- ✓ Preparations for the manufacture and delivery of new prototype ColoSTAT® test kits.



**Phase 3** activities will be the delivery of the new prototype ColoSTAT® test kits in line with future IVDR product registration and this is expected to be delivered to Rhythm in second half of CY'24.

#### Patent Extension for ColoSTAT®

The current patent review and renewals of ColoSTAT® in preferred markets - will lengthen patent protection by more than a decade to early 2042.

## Regulatory

**ISO** certification to the International Standard for In-Vitro Diagnostics and Medical Devices (ISO 13485:2016) maintained - Subsequent to period end the Company announced on 23 April, that the Company had retained ISO certification for its Quality Management System for a sixth consecutive year. ISO 13485:2016 is the internationally recognised quality standard to ensure the consistent design, development, manufacture, and sale of medical devices that are safe for their intended purposes. The ISO certification was conducted by the British Standards Institution (BSI) and remains a critical component of the Company's commercial and market entry strategies.

## **Expert / Advisory**

Initial Clinical Advisory Board (CAB) meeting – The CAB establishment was announced to the ASX on the 19 March 2024. The initial meeting was held on the 3rd of April, with valuable feedback given on ColoSTAT® and its entry into commercialisation activities. The CAB is advising upon critical data and outcome measures, to ensure ColoSTAT® IVDR readiness for the Company's registration and launch in different international markets.

## Review of Prior (1H'FY24) Stated Value Inflection Points

- ✓ Appointment of a suitably qualified CEO COMPLETED
- ✓ ISO Audit COMPLETED
- ✓ Progress updates from our new, U.S.A. based CMO on ColoSTAT® development PHASE 1
   COMPLETED
- ✓ New patent applications lodgement, extending the duration for ColoSTAT® protection in a broader set of jurisdictions – UNDERWAY
- ✓ Establishment of ColoSTAT® Clinical Advisory Board COMPLETED

## Milestones we expect to deliver before the end of CY'24:

- Lodgement and receipt of RDTI returns;
- Further progress updates from our U.S. based CMO on ColoSTAT®, with initial delivery of newly designed kits being delivered to our Australian office; and
- Further detail on patent applications lodgement, extending the duration for ColoSTAT® protection.

- ENDS -

Authorised for release by the Board.



#### For further information contact us via investor@rhythmbio.com:

| Mr. Otto Buttula   | Mr. Guy Carisbrooke  |
|--------------------|----------------------|
| Executive Chairman | Financial Controller |

#### **About Rhythm Biosciences**

Rhythm Biosciences Ltd (ASX: RHY) is an Australian innovative, medical diagnostics company aimed at delivering simple, affordable blood tests for accurate and early detection of cancers. Rhythm is focused on improving patient outcomes through detection at the earliest possible stage, reducing the global burden of cancer and saving lives.

Rhythm Biosciences is committed to working with likeminded global partners to achieve commercialisation and distribution of these simple solutions.

The company was founded in 2017 and is headquartered in Melbourne, Australia. For more information, visit rhythmbio.com and follow the company on LinkedIn and Twitter.

#### **About ColoSTAT®**

Colorectal cancer (CRC), also referred to as bowel cancer, is the second leading cause of cancer deaths globally. If diagnosed early, colorectal cancer is curable. The ColoSTAT® Test-Kit is Rhythm Bioscience's simple blood-based test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood of CRC. The test is an alternative for individuals who are unable or unwilling to participate in current screening programs. It is being updated to meet the IVDR (In vitro diagnostic medical devices regulation) regulatory standards.

The ColoSTAT® Test-Kit is based on research from Australia's CSIRO and is patent protected internationally. It has the potential to play a key role in reducing the mortality rate and healthcare costs associated with colorectal cancer.

## **Appendix 4C**

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

#### Name of entity

| RHYTHM BIOSCIENCES LIMITED            |  |  |  |
|---------------------------------------|--|--|--|
| ABN Quarter ended ("current quarter") |  |  |  |
| 59 619 459 335 31 MARCH 2024          |  |  |  |

| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date<br>(9 months)<br>\$A'000 |
|-----|------------------------------------------------|----------------------------|---------------------------------------|
| 1.  | Cash flows from operating activities           |                            |                                       |
| 1.1 | Receipts from customers                        |                            |                                       |
| 1.2 | Payments for                                   |                            |                                       |
|     | (a) research and development                   | (1,093)                    | (3,582)                               |
|     | (b) product manufacturing and operating costs  |                            | (1,168)                               |
|     | (c) advertising and marketing                  |                            |                                       |
|     | (d) leased assets                              |                            |                                       |
|     | (e) staff costs (not included above)           | (228)                      | (600)                                 |
|     | (f) administration and corporate costs         | (382)                      | (1,129)                               |
| 1.3 | Dividends received (see note 3)                |                            |                                       |
| 1.4 | Interest received                              | 3                          | 41                                    |
| 1.5 | Interest and other costs of finance paid       | (1)                        | (3)                                   |
| 1.6 | Income taxes paid                              |                            |                                       |
| 1.7 | Government grants and tax incentives           |                            | 1,690                                 |
| 1.8 | Other – insurance prepayment                   | (177)                      | (177)                                 |
| 1.9 | Net cash from / (used in) operating activities | (1,878)                    | (4,928)                               |

| 2.  | Cas | sh flows from investing activities |     |      |
|-----|-----|------------------------------------|-----|------|
| 2.1 | Pay | ments to acquire or for:           |     |      |
|     | (a) | entities                           |     |      |
|     | (b) | businesses                         |     |      |
|     | (c) | property, plant and equipment      | (2) | (82) |
|     | (d) | investments                        |     |      |
|     | (e) | intellectual property              |     |      |
|     | (f) | other non-current assets           |     |      |

ASX Listing Rules Appendix 4C (17/07/20)

Page 1

| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date<br>(9 months)<br>\$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 | (2)                        | (82)                                  |

| 3.   | Cash flows from financing activities                                                    |       |       |
|------|-----------------------------------------------------------------------------------------|-------|-------|
| 3.1  | Proceeds from issues of equity securities (excluding convertible debt securities)       | 2,484 | 2,484 |
| 3.2  | Proceeds from issue of convertible debt securities                                      |       |       |
| 3.3  | Proceeds from exercise of options                                                       |       | 270   |
| 3.4  | Transaction costs related to issues of equity securities or convertible debt securities | (73)  | (73)  |
| 3.5  | Proceeds from borrowings                                                                |       |       |
| 3.6  | Repayment of borrowings                                                                 | (23)  | (69)  |
| 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                                          | 2,388 | 2,612 |

| 4.  | Net increase / (decrease) in cash and cash equivalents for the period |         |         |
|-----|-----------------------------------------------------------------------|---------|---------|
| 4.1 | Cash and cash equivalents at beginning of period                      | 1,218   | 4,124   |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above)       | (1,878) | (4,928) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above)       | (2)     | (82)    |

| Con | solidated statement of cash flows                                | Current quarter<br>\$A'000 | Year to date<br>(9 months)<br>\$A'000 |
|-----|------------------------------------------------------------------|----------------------------|---------------------------------------|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | 2,388                      | 2,612                                 |
| 4.5 | Effect of movement in exchange rates on cash held                |                            |                                       |
| 4.6 | Cash and cash equivalents at end of period                       | 1,726                      | 1,726                                 |

| 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<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-----------------------------|
| 5.1 | Bank balances                                                                                                                                                     | 1,726                      | 1,218                       |
| 5.2 | Call deposits                                                                                                                                                     |                            |                             |
| 5.3 | Bank overdrafts                                                                                                                                                   |                            |                             |
| 5.4 | Other – short term deposit                                                                                                                                        |                            |                             |
| 5.5 | Cash and cash equivalents at end of quarter (should equal item 4.6 above)                                                                                         | 1,726                      | 1,218                       |

| 6.  | Payments to related parties of the entity and their associates                          | Current quarter<br>\$A'000 |
|-----|-----------------------------------------------------------------------------------------|----------------------------|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 93                         |
| 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 salaries.

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.

| 7.  | Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.                                                                                                                       | Total facility<br>amount at quarter<br>end<br>\$A'000 | Amount drawn at<br>quarter end<br>\$A'000 |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------------------|
| 7.1 | Loan facilities                                                                                                                                                                                                                                                                                                                             |                                                       |                                           |
| 7.2 | Credit standby arrangements                                                                                                                                                                                                                                                                                                                 |                                                       |                                           |
| 7.3 | Other (please specify)                                                                                                                                                                                                                                                                                                                      |                                                       |                                           |
| 7.4 | Total financing facilities                                                                                                                                                                                                                                                                                                                  |                                                       |                                           |
| 7.5 | Unused financing facilities available at qu                                                                                                                                                                                                                                                                                                 | uarter 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. |                                                       | itional financing                         |

| 8.  | Estimated cash available for future operating activities                                    | \$A'000                    |
|-----|---------------------------------------------------------------------------------------------|----------------------------|
| 8.1 | Net cash from / (used in) operating activities (item 1.9)                                   | (1,878)                    |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6)                                         | 1,726                      |
| 8.3 | Unused finance facilities available at quarter end (item 7.5)                               | -                          |
| 8.4 | Total available funding (item 8.2 + item 8.3)                                               | 1,726                      |
| 8.5 | Estimated quarters of funding available (item 8.4 divided by item 8.1)                      | 0.92                       |
|     | Note: if the entity has reported positive net operating cash flows in item 1.9, answer item | 8.5 as "N/A". Otherwise. a |

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: It is expected that the net operating cash out flow will be relatively stable over the coming quarter, and be further assisted with an R&D Tax Incentive refund.

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: The Company is currently working with advisors to place the remaining shortfall shares with a potential funds value of over \$4m under the recent Rights Issue Offer.

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: On the basis of the responses above, the Company expects to be able to continue its operations and meet its business objectives as required under the Corporations Act.

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.

## **Compliance statement**

- 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:          | 30 APRIL 2024 |
|----------------|---------------|
|                |               |
| Authorised by: | 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.
- 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.