## ASX Announcement

29 July 2024

# RHYTHM BIOSCIENCES

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

## Highlights

- ✓ Significant progress made on re-engineering ColoSTAT<sup>®</sup> assay into a simpler, higher quality multiplex antibody assay.
- ✓ Update of clinical strategy to include the indication of triage for patients symptomatic for bowel disease and with higher-than-average risk of colon cancer.
- $\checkmark$  Significant upgrade of quality systems with migration to eQMS and strengthening of team to ensure consistent quality.

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 30 June 2024. This report includes ongoing Company development activities aimed at progressing the development and commercialisation of ColoSTAT®, Rhythm's simple blood test for the detection of colorectal cancer ultimately aimed at global mass market screening, in addition to leveraging the Company's technologies into a range of other cancer diagnostic initiatives.

#### Corporate

Board Composition and Future Initiatives – As previously foreshadowed, effective 31 May 2024, Mr. Otto Buttula reverted to a non-executive position, formally relinquishing all executive duties. This followed the commencement of Dr. David Atkins as Chief Executive Officer on 13 May 2024. Dr. David Atkins assumed day-to-day executive leadership, with all material handover activities completed by the end of May 2024.

In addition, the Board has formally initiated a Board composition review in recognition of the evolution of the business. The Board will engage a qualified third party to assess and advise on a renewed and appropriate board structure that will support the business as it updates and executes its strategy over the coming years.

**Rights Issue** – The final phase of the Company's Rights Issue (as announced to the ASX on 9 February 2024) closed on 14 June 2024, raising a further \$623k, bringing the total to ~\$2.75m. Investors secured further investment in the Company on the same terms as the Rights Issue for entitlements not subscribed for (Shortfall Shares).

**R&D Tax Incentive (RDTI)** – The Company is concluding deliberations with its Tax Advisers and Auditors in relation to resubmitting a portion of its' FY23 R&D Tax Incentive claim for overseas activities, which is expected to be resolved favourably and in the current quarter.

ACN 619 459 335 ASX: RHY

Rhythm Biosciences Ltd Australian Registered Address Bio21 Molecular Science & Biotechnology Institute 30 Flemington Road Parkville VIC 3010 Australia

Directors Otto Buttula Sue MacLeman Trevor Lockett Louis Panaccio

Non-Executive Chairman Non-Executive Deputy Chair Non-Executive Director Non-Executive Director

www.rhythmbio.com

T +61 3 8256 2880 E info@rhythmbio.com



Work has also commenced and progressed on the preparation of the R&D Tax Incentive Claim for FY24, expected to be lodged in the current quarter, and received within the 2024 Calendar Year. In order to meet ongoing requirements, the Company is in discussions to establish a Financing Facility with an external and independent lender, secured against current and future RDTI refunds.

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

**Bioshares presentation** – the Company was invited to present at the Bioshares 18<sup>th</sup> Biotech Summary and Dr Atkins gave an overview of how the Company was increasing focus on customer feedback and how this was shaping future priorities for the businesses.

#### **Product Development and Manufacturing**

**Engagement of Contract Manufacturing Organisation (CMO)** – Quansys has been engaged to redesign and develop a multiplex version of ColoSTAT<sup>®</sup> that has the potential to be of materially lower cost, simpler to use and to be of a more consistent quality.

Quansys employs a stage-gate development process and **Phase 1** technology transfer and initial feasibility has now been completed. **Phase 2** activities focus on optimisation of the assay design coupled with extensive analytical testing and the Company expects to receive initial "alpha" kits for preliminary clinical evaluation in the current quarter (Q1 FY'25).

A full-time, experienced Operations and Project Manager has been recruited and onboarded at the Company to continue to oversee and manage the implementation of this important development program. Finally, the entire Company Quality Management System (QMS) has been migrated to an eQMS ('electronic' QMS) system to support more effective use of the QMS in guiding product design and development, in addition to regulatory requirements.

#### **Clinical Indication Prioritisation**

The Company benefits from an experienced and engaged **Clinical Advisory Board** and ongoing discussions have led the Company to explore opportunities for ColoSTAT<sup>®</sup> as a screening test in higher risk populations such as those individuals who present to a primary health care practitioner with symptoms of lower bowel disorders. The Company is evaluating whether ColoSTAT<sup>®</sup> could be used to prioritise or "triage" the use of colonoscopy to investigate the presence of cancer in the highest risk symptomatic patients. While general population screening is still a Company priority, an intermediate commercial application in the triage market could represent an attractive intermediate market opportunity.

#### **Platform Expansion**

The Company previously reported on plans to expand the cancer diagnostic "menu" that it can support beyond ColoSTAT<sup>®</sup> and colorectal cancer. Results have been presented for lung and breast cancer and the Company has collaborated with partners (Agilex, Baker Medical & Nexomics from Peter Mac).



In regard to gastric, gastric cancer, analysis of the raw data will be completed in the coming weeks, and we look forward to sharing conclusive results in the coming quarter.

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

- ✓ Further progress updates from our U.S. based CMO on ColoSTAT<sup>®</sup>
- ✓ Significant increase in quality capability within product design and development processes.

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

- Receipt of RDTI returns.
- Delivery of newly designed multiplex kits to our Australian office by Quansys, our US-based CMO and completion of in-house analytical validation.
- Conclusion of first stage of the cancer indication expansion program following completion of analysis of data form initial cohort of 600 patient samples.
- Finalisation of the triage application market access strategy for the next generation ColoSTAT<sup>®</sup> assay.

#### - ENDS -

#### Authorised for release by the Board.

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

Dr. David Atkins	Mr. Guy Carisbrooke
Chief Executive Officer	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<sup>®</sup> 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.

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# 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")

Quarter ended ("current quarter")

59 619 459 335

30 JUNE 2024

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(785)	(4,367)
	(b) product manufacturing and operating costs		(1,168)
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs (not included above)	(226)	(826)
	(f) administration and corporate costs	(216)	(1,345)
1.3	Dividends received (see note 3)		
1.4	Interest received	11	52
1.5	Interest and other costs of finance paid	(1)	(4)
1.6	Income taxes paid		
1.7	Government grants and tax incentives		1,690
1.8	Other – insurance prepayment		(177)
1.9	Net cash from / (used in) operating activities	(1,217)	(6,145)

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

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 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		(82)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	261	2,745
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	(37)	(110)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(24)	(93)
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	200	2,812

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,726	4,124
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,217)	(6,145)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		(82)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	200	2,812
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	709	709

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	709	1,726
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)	709	1,726

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	87
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
Paym	ents in 6.1 relate to Director fees and salaries.	
	f any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ ation for, such payments.	le a description of, and an

7.	<b>Financing facilities</b> 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 amount at quarter end \$A'000	Amount drawn at quarter end \$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	arter end	
7.6	Include in the box below a description of eac rate, maturity date and whether it is secured facilities have been entered into or are propo include a note providing details of those facil	or unsecured. If any add used to be entered into af	itional financing

8.	Estim	ated cash available for future operating activities	\$A'000
8.1	Net ca	sh from / (used in) operating activities (item 1.9)	(1,217)
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	709
8.3	Unuse	d finance facilities available at quarter end (item 7.5)	-
8.4	Total a	vailable funding (item 8.2 + item 8.3)	709
8.5	Estima item 8	ated quarters of funding available (item 8.4 divided by .1)	0.58
		the entity has reported positive net operating cash flows in item 1.9, answer ite r the estimated quarters of funding available must be included in item 8.5.	em 8.5 as "N/A". Otherwise, a
8.6	If item	8.5 is less than 2 quarters, please provide answers to the follo	wing questions:
	8.6.1 Does the entity expect that it will continue to have the current level of net operatin cash flows for the time being and, if not, why not?		
	Answe	r: No, current quarter cash outflows incorporated arrears and r for non-recurring projects. Hence current budgetary planning decline from the quarterly cash outflows recorded over the pa	g expects a significant
	8.6.2	Has the entity taken any steps, or does it propose to take any cash to fund its operations and, if so, what are those steps are believe that they will be successful?	
	Answer: The company has a proven track record of raising funds as and when needed. Nonetheless, the Company is in the process of securing a finance facility with an external independent lender, secured against current and future R&D Tax Incentive refunds to be received by the Company, which are expected to be significant. The Company is also evaluating opportunities to apply for non-dilutive funding through government and other grants programs. The Company believes that the funding available from each of these initiatives will be sufficient to fund the Company's current ongoing initiatives and operations, and to meet its business objectives.		

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 has funding sources available and hence the Company expects to be able to continue its operations and meet its business objectives as required.

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**

- 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 JULY 2024.....

Authorised by: .....BY THE BOARD..... (Name of body or officer authorising release – see note 4)

#### 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.