

Rhythm Biosciences Quarterly Report – March 2023

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) is pleased to provide an update on its activities for the quarterly period ended 31 March 2023, including subsequent events.

The predominant activities undertaken centred around progressing the commercialisation of ColoSTAT[®], its simple blood test for the detection of colorectal cancer, aimed at global mass market screening. Other corollary activities are aimed at leveraging ColoSTAT's[®] cancer detecting markers in expanding the Company's platform, initially targeting five further cancers for simple blood screening.

Regulatory

- **Update to TGA submission**

As per the announcement released to the ASX on 6 March 2023, the Company is addressing the feedback from the Australian Therapeutic Goods Administration (TGA) assessment. Following the withdrawal of the TGA application, the Company is positioning for a new application addressing the full list of TGA questions. Further updates will be announced to the ASX as the new application and submission progresses.

The withdrawal of the TGA submission will not impact proposed market entry activities into CE Mark conforming territories (Europe), nor additional international markets such as the USA.

Commercialisation

- **Partnering / commercialisation deals (Domestic and International)**

As previously indicated, Rhythm is assessing its partners within each of the regions as a short-term objective to obtain commercially favourable terms that will deliver solid growth in:

- ✓ AUSTRALIA;
- ✓ NEW ZEALAND;
- ✓ SOUTH AFRICA;
- ✓ UNITED KINGDOM; and
- ✓ U.S.A.

Manufacturing

- **Manufacturing scale up**

- ✓ Rhythm continues to work with Biotem as our European manufacturing partner;
- ✓ A U.S.A. based manufacturing company has supplied a feasibility manufacturing batch which has delivered the expected outcomes and scale-up activities have now been planned for 1H'24. This U.S.A. manufacturer has been selected to support our future market entry across the American continents;
- ✓ Contract Manufacturers are continually audited in line with Rhythm, ISO and global manufacturing requirements; and
- ✓ The Company intends to continue examining the feasibility of manufacturing domestically.

Rhythm Biosciences Ltd
 ACN 619 459 335
 ASX: RHY

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Australian Registered Address

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Directors

Otto Buttula	Executive Chairman
Trevor Lockett	Executive Director
Rachel David	Non-Executive Director
Louis Panaccio	Non-Executive Director
Sue MacLeman	Non-Executive Director

Marketing

▪ **ColoSTAT® marketing program**

Rhythm progressed several initiatives related to product marketing, partnerships, and potential customer engagement activities, which included:

- ✓ The final stages of a new Company website expected to be delivered imminently;
- ✓ Conducted further market surveys to provide awareness and information regarding ColoSTAT®;
- ✓ The Company has continued to work with potential partners in both South Africa and the United Kingdom to evaluate the CRC market; and
- ✓ The Company 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 output generates an interactive model that highlights specific benefits of ColoSTAT® which can be discussed with Medical Practitioners, Government, Private Health Insurers and other payors alike.

Core Technology

▪ **Final Study Reports**

- Rhythm is advancing the identification of the most applicable journals for publication of the Study 7 clinical trial results and Health Economics Model.

▪ **ColoSTAT®**

- ✓ The Company continues to produce its core kit across two global manufacturers (one contracted). The kit involves generating reproducible and scalable outcomes across the validation batches.
- ✓ The ColoSTAT® technology has been patented across 23 countries, and the Company continues to pursue further patents in the interest of its market potential.

▪ **Platform Expansion Program with Other Cancers**

- ✓ The Company continues to pursue its technology platform expansion program leveraging the key lead biomarker for its initial bowel cancer screening product, ColoSTAT®.
- ✓ Leading biomarkers have been identified as potentially critical to progress research and development into other target cancers: Breast, Lung, Cervical, Pancreatic and Gastric; and
- ✓ The Company is actively working with additional partners to evaluate practical biomarker potentials in other cancers.

Operational

▪ **ISO Certification**

As advised to the ASX on the 15 February 2023, Rhythm announced that it was pleased to confirm it had successfully retained its ISO certification for its Quality Management System for a fifth consecutive year.

Board & management

- **Highly regarded MedTech leader Ms Sue MacLeman appointed Non-Executive Director**
As per the announcement to the ASX on 31 January 2023, Rhythm announced the appointment of Ms Sue MacLeman to the Board as an independent Non-Executive Director.

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 2023, pertain to payments to directors for fees, salary and superannuation.

Corporate

- Cash at bank at the end of the quarter was \$6.8M.
- Rhythm received an additional \$374k refund for Research and Development activities in March 2023 for the financial years FY'21 and FY'22; and
- As per 27 February 2023, Rhythm announced the change of its provider for shareholder registry services from Link Market Services to Automic Pty Ltd.

Subsequent to period end:

- As announced to the ASX on 6 April 2023, both abstracts submitted on ColoSTAT® at the 2023 Annual Meeting of the American Society for Clinical Oncology (ASCO) have been accepted.

The abstracts outlining the clinical data and economics for the adoption of ColoSTAT® in the USA will be available to an expected attendance of more than 40,000 healthcare professionals in the event. The event showcases the latest innovations in cancer research and education, and is being held in Chicago, Illinois from 2-6 June 2023. More than 6,500 submissions were reviewed by the Scientific Program Committee and ASCO's Leadership team for potential presentation at a poster session.

- As announced to the ASX on 19 April 2023, Mr Glenn Gilbert resigned as Chief Executive Officer and Managing Director. Mr Otto Buttula will assume more executive duties along with the expanded executive management team.

Review of Prior (Q3FY'23) Stated Value Inflection Points

- TGA approval for ColoSTAT® for sale in the Australian market – **COMPANY DECISION TO WITHDRAW**
- Regulatory approvals in additional countries – **COMMENCED & ONGOING**
- Commercialisation / partnering agreements with third parties – **COMMENCED & ONGOING**
- Progress our technology expansion program – **COMMENCED & ONGOING**

Future Value Inflection Points

Matters we expect to deliver upon in the next quarter include:

- Additional manufacturer approved on the Rhythm's Quality Management System (QMS);
- Regulatory approvals in additional countries;
- Commercialisation / partnering agreements with third parties; and
- Progression of the Company's technology platform expansion program.

- ENDS -

Authorised for release by the Board.

For further information contact:

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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 test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood presence of CRC. The test can be used as an alternative for individuals who are unable or unwilling to participate in current screening programs.

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

59 619 459 335

Quarter ended ("current quarter")

31 MARCH 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(2,072)	(5,587)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(132)	(516)
(f) administration and corporate costs	(293)	(1,016)
1.3 Dividends received (see note 3)		
1.4 Interest received	76	180
1.5 Interest and other costs of finance paid	(2)	(6)
1.6 Income taxes paid		
1.7 Government grants and tax incentives	375	3,096
1.8 Other		
1.9 Net cash from / (used in) operating activities	(2,048)	(3,849)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(30)	(85)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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	(30)	(85)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		3,216
3.4	Transaction costs related to issues of equity securities or convertible debt securities		(18)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(21)	(63)
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	(21)	3,135

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,850	7,550
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,048)	(3,849)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(30)	(85)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(21)	3,135
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	6,751	6,751

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	6,751	3,850
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other – short term deposit		5,000
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	6,751	8,850

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	208
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<p>Payments in 6.1 relate to Director fees and salaries.</p> <p><i>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.</i></p>		

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
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 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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,048)
8.2 Cash and cash equivalents at quarter end (item 4.6)	6,751
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	6,751
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.3
<i>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.</i>	
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	
<i>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.</i>	

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:

Authorised by:PAUL SMITH.....
 (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.