

Rhythm Biosciences Quarterly Report – June 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 30 June 2023.

Commercialisation

▪ **Commercial Launch - UK**

As previously announced to the ASX on 24 May 2023, Rhythm signed a Strategic Partnership with London-based medical technology consultancy and provider, LINK Medical Solutions Ltd. Initially LINK have established Key Opinion Leaders (KOL) for ColoSTAT® in the UK to investigate the positioning of Rhythm's test in the UK market.

RHY have established a 100% owned UK subsidiary (refer 3 July 2023) and have obtained the UK CA mark certification (17 May 2023) to enable a successful ColoSTAT® market launch.

Currently, in the UK, more than 61% of all diagnosed bowel cancer cases are outside the screening population (60-74 years of age). With the recent passing of BBC News presenter, George Alagiah,¹ at the age of 67, who was diagnosed in 2014 with stage four bowel cancer (aged 58), and in 2022 with Dame Deborah James,² dying at the age of 40, it has raised the public awareness that bowel cancer is not an "old persons disease". This gives ColoSTAT®, a simple blood-based test, the opportunity to address the unmet need outside of the UK screening population.

▪ **ColoSTAT® market awareness program - Australia**

Rhythm continues to identify opportunities to position ColoSTAT® in the clinical practice through increased market awareness and collaboration with key stakeholders.

Recent publications by the Australian Institute of a Health and Welfare (**AIHW**)³ identified that the current screening participation rate (50-74 years) in Australia has declined to 40.9% over the past 2 years (2.4 million people participated in the screening program of 6.6 million invited minus 0.5 million who opted out). 4.2 million people of the screening population did not complete the Faecal Immunochemical Test (FIT). Further, of the 15,367 people diagnosed with bowel cancer in Australia, more than 52% were outside the screening population (>12% were under the aged of 50, and >39% were above the screening age.)³

RHY progressed several initiatives related to its affiliation and partnership with the Victorian Government, Cancer Council, and Bowel Cancer Australia holding the Biggest Morning Tea, to raise awareness on ColoSTAT® as an alternative to current screening practices and expand the participation rate.

▪ **ColoSTAT® commercial opportunities**

Further initiatives include:

- ✓ Development initiatives focussed upon market entry into New Zealand & South Africa;
- ✓ Automation of the ColoSTAT® immunoassay with a commercial pathology laboratory;
- ✓ Conducted a consumer survey in Australia and New Zealand, identifying that over 71% prefer a blood-based test instead of FIT, with “Ease and Simplicity” and “avoidance of the Yuk factor” being the main reasons;
- ✓ Conducted an advisory board with physicians and payers from Australia and the UK;
- ✓ As per 6 June 2023 announcement, Rhythm presented pivotal clinical data for ColoSTAT® at the American Society of Clinical Oncology (ASCO) where more than 40,000 healthcare professionals attended. This highlighted that the prospective, multi-centre clinical study achieved its primary endpoint with ColoSTAT® demonstrating a sensitivity of 81% and Specificity of 91% versus the gold standard for Bowel Cancer, Colonoscopy.

▪ **Manufacturing scale up**

- ✓ As per this 4C, Rhythm continues to build a raw material inventory, with stock on hand (~AUD\$3 million) at the global Contract Manufacturing Organisation (CMO), with this expected to meet the initial unmet demand in the anticipated UK and other market entries;
- ✓ A U.S.A based manufacturer has been engaged to deliver a pilot batch post successful feasibility manufacturing; and
- ✓ The Company continues to review further global and local CMO’s in line with the strategic plan identified in the Investor Presentation on 20 June 2023.

▪ **Update to TGA submission**

As per announcement on 20 June 2023, the Company is preparing to submit a revised regulatory approval into the Australian Market to the Therapeutic Goods Administration (TGA) incorporating the feedback to the Company (refer 6 March 2023). The revised application for the TGA will provide the Company the additional requirements to satisfy the changes for the European In Vitro Diagnostic Medical Device (IVDR) transition to be enforced on 26 May 2026.⁴

Core Technology

▪ **ColoSTAT®**

- ✓ The Company continues to produce its core kit across multiple contracted global manufacturers. The kit involves generating reproducible and scalable outcomes across the validation batches.
- ✓ The ColoSTAT® technology has further renewed its patents across 21 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;

- ✓ As per 19 June 2023, an update was provided to the market regarding the partnership with Nexomics, at Peter MacCallum Cancer Centre; and
- ✓ The Company is actively working with additional partners to evaluate practical biomarker potentials in other cancers.

Board & Management

- As per 19 April 2023, CEO, Mr Glenn Gilbert resigned from the Company.

Following Period-End

- Highly regarded MedTech leader Ms Sue MacLeman appointed Independent Deputy Chair**

As per the announcement on 4 July 2023, Rhythm announced the appointment of Ms Sue MacLeman to the independent Deputy Chair position and will assume the Chair of the Audit and Risk Committee and the Remuneration and Evaluation Committee.

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

Corporate

- Cash at bank at the end of the quarter was \$4.1M.
- Raw Material Stock on Hand was \$3.0M
- Rhythm received verification of the EMDG grant for \$12k for export activities.
- As per 25 May 2023, the Company received an ASX query regarding the Share Trading Policy.
- As per 23 June 2023, RHY provided an update to the Securities Trading Policy to incorporate ASX Listing Rules 12.10 and 12.12.
- Rhythm received a TGA Freedom of Information (FOI) query on 31 May 2023 relating to the ColoSTAT® application and TGA disclosure log. The Company has responded to the query.

Review of Prior (Q4FY'23) Stated Value Inflection Points

- UK partnership with LINK Medical Solutions Ltd – **COMMENCED & ONGOING**
- UK Regulatory approvals (CA certification) achieved – **COMPLETED**
- 100% owned UK Subsidiary established – **COMPLETED**
- Progress our technology expansion program with Nexomics – **COMMENCED & ONGOING**

Future Value Inflection Points

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

- Commence Automation Project;
- Research and Development Tax Incentive (expected ~\$3.8million);
- Financial Year End, Audit and Annual report and Annual General Meeting (10th October at 11.00am);
- 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:

Mr Otto Buttula Executive Chairman	Mr Paul Smith CFO & Company Secretary
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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.

References

- 1 <https://www.theguardian.com/society/2023/jul/24/what-is-bowel-cancer-and-how-can-i-spot-early-signs-george-alagiah>
- 2 <https://www.bbc.com/news/uk-61451495>
- 3 AIHW Publication - <https://www.aihw.gov.au/reports/cancer-screening/nbcsp-monitoring-2023/summary>
- 4 <https://www.johner-institute.com/articles/health-care/new-ivdr-transitional-period/>

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")

30 JUNE 2023

Consolidated 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	(917)	(5,379)
(b) product manufacturing and operating costs	(1,868)	(2,993)
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(145)	(661)
(f) administration and corporate costs	(231)	(1,247)
1.3 Dividends received (see note 3)		
1.4 Interest received	49	229
1.5 Interest and other costs of finance paid	(1)	(7)
1.6 Income taxes paid		
1.7 Government grants and tax incentives		3,096
1.8 Other		
1.9 Net cash from / (used in) operating activities	(3,113)	(6,962)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(14)	(99)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

Consolidated 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	(14)	(99)

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	525	3,741
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	(22)	(85)
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	503	3,638

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,751	7,550
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,113)	(6,962)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(14)	(99)

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)	503	3,638
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	4,127	4,127

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	4,127	6,751
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)	4,127	6,751

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	289
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 and Managing Director resignation. <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>		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	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 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)	(3,113)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,127
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,127
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.33
<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: Net operating cash outflows have increased recently due to stocks of raw materials for market entry requirements. It is expected that the net operating cash out flow will reduce over the coming quarter and be further assisted with the 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 focused on generating working capital through the current stock availabilities and converting these from stock to cash inflows over the coming 2 quarters.	

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: 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

- 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:31 JULY 2023.....

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.