

Rhythm Biosciences Quarterly Report – December 2023

Highlights

- **New Chief Executive Officer search formally underway, engendering significant interest;**
- **Clear pathway established for ColoSTAT[®], with new U.S. based Contract Manufacturing Organisation (CMO) engaged to meet more rigorous IVDR standards;**
- **ColoSTAT[®] Automation project with Nutripath and Tecan completed;**
- **Platform expansion – initial outcomes in Lung Cancer positive;**
- **1st Tranche of R&D Tax Incentive received, new secondary submission underway; and**
- **Manuscript for ColoSTAT[®] clinical performance study submitted.**

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (**Rhythm** or the **Company**) provides the following update on its activities for the quarterly period ended 31 December 2023.

Strategy Update

As foreshadowed at the 2023 Annual General Meeting (AGM), following an in-depth strategic review (utilising both internal and contracted, external resources) on 18 December 2023, the Company released a synopsis of its resulting, Board approved, key decisions.

These included:

- **Appointment of a suitably qualified Chief Executive Officer (CEO)** – this process is formally underway, with a large number of interested applicants being reviewed. As disclosed on 15 November 2023, following a handover period, the current Executive Chairman, Mr Otto Buttula, will relinquish his executive position and resume duties as a Non-executive Director.
- **Reclassification of ColoSTAT[®] kits in inventory to Research Use Only (RUO), rather than for commercial sales** – following an executive recommendation, the Board has agreed that the Company's existing IVDD ColoSTAT[®] kits would not be made available for commercial sales, but rather for RUO.
- **Manufacture of a consistent, newly designed ColoSTAT[®] kit**, encompassing cost savings and automation features and importantly meeting new regulatory IVDR standards.
- **Engagement of a new U.S. based Contract Manufacturing Organisation (CMO) to undertake design and development work on ColoSTAT[®] completing IVDR transition works; following which Rhythm intends to obtain regulatory approvals for the new IVDR compliant kits** - this is aimed to replace the Company's current IVDD regulatory approvals (CE & CA Mark and Medsafe), which we intend to de-register in February 2024. Further, the Company continues to evaluate various options to participate in the U.S. market, despite FDA regulatory uncertainty.
- **The IVDR transition work and newly manufactured kits** remains the Company's highest priority for CY24.
- **Transfer and implementation of recently adopted IVDR transition works to the Company's technology pipeline including in breast, lung and gastric cancer.**
- **Reviewing the R&D tax incentive (RDTI), following the receipt of Tranche 1 of \$1.69m** – in particular the Company is planning to formally lodge an amended RDTI claim for its international component of R&D given the current kits reclassification to RUO.

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 ASX: RHY

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Directors

Otto Buttula	Executive Chairman
Sue MacLeman	Independent, Deputy Chair
Trevor Lockett	Non-Executive Director
Louis Panaccio	Non-Executive Director

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- **Implementation of a significant cost reduction strategy** - consistent with the Company's strategic intent of implementing the new regulatory standards in Europe and its proposed adoption in Australia, it was resolved to realign current operations and resources to best realise the Company's objectives in adopting the new stringent IVDR (In Vitro Diagnostic Medical Device Regulation) requirements for all products in development.

This has involved the Company taking decisive action to reduce corporate overheads, via an organisational restructure and the engagement of contracted external expertise to assist the reduced and more focused internal team. Despite incurring some higher one-off initial expenses, significant progress has been achieved in lowering fixed, ongoing operating costs, with further savings expected to be realised as the cost base is realigned to meet the new strategic direction.

Activities going forward will be highly focused on the high-priority ColoSTAT® completion, and platform expansion, where resources and opportunities allow.

Commercialisation

- **Advisory Board with UK Key Opinion Leaders**

Due to the IVDR transition works, the next Advisory Board meeting with Link Medical and influential UK based medical specialists to discuss and advise on how to position and utilise ColoSTAT® in the UK, is deferred until 4Q'FY24.

- **Automation Project Completed**

As announced on 13 September 2023, Rhythm executed an Automation Agreement with Melbourne-based, medical laboratory, Nutripath Pty Ltd a specialty clinical laboratory, that supports healthcare providers in health and wellbeing pathology testing.

Collaborating with Nutripath and one of its diagnostic machine vendors, Tecan Australia Pty Ltd (a subsidiary of Swiss based Tecan Group Ltd), the parties streamlined the previously manual process of ColoSTAT® to the automated Tecan EVO machine.

The ColoSTAT® 5-biomarker immunoassay was successfully transferred to the Tecan EVO machine, and the total run time for 39 samples, was at < 6 hours. This was achieved with only one scientist, instead of the 3 scientists normally required to run the complete ColoSTAT® test manually.

Core Technology

- **Platform Expansion Lung Cancer**

As previously announced (ASX: RHY - 15 December 2022), together with the Baker Institute, Rhythm had identified a 5-biomarker combination that exhibits an effective correlation with various stages of lung cancer.

On 24 November 2023, the Company released the positive outcomes of preliminary data from the Baker Institute on its lung cancer diagnostic test. A 5 biomarker-combination had identified **above 85% Sensitivity and 90% Specificity**.

The preliminary assessment of 17 biomarkers was performed by the Baker Institute in a "research use only" feasibility immunoassay study to evaluate these blood-based biomarkers from 70 lung cancer patients and 71 healthy volunteers. This preliminary R&D has identified an important biomarker combination that can distinguish between patients with lung cancer and healthy controls, with >85% sensitivity and >90% specificity (P ≤0.00001).

These encouraging results warrant confirmation in a larger population and justify the continuation and advancement of the project. Therefore, verification of these results would support the case for investment in a new R&D program to develop, validate, clinically evaluate the performance of the biomarkers, and translate these results into a commercially scalable, proprietary blood test to detect lung cancer early when it is most responsive to potentially curative treatments.

Corporate

- On 14 November 2023, the Company advised that it had received the first tranche of its research and development tax incentive (RDTI) totalling \$1.69 million. This forms part of the Australian government's R&D tax incentive program. This initial receipt of the R&D tax incentive recognises the Australian based activities undertaken by Rhythm during the financial year ended 30 June 2023. The receipt of the \$1.69m, is expected to be complemented by a further receipt for research and development activities undertaken overseas. The second receipt is expected in 2024, once verified and lodged by the Company's tax advisers.
- On 15 November 2023, the Company announced executive management changes, including:
 - The resignation, for personal reasons, of Mr Paul Smith as Chief Financial Officer and Joint Company Secretary;
 - Dr Trevor Lockett ceasing his executive director duties as Technical Director on 15 December 2023;
 - The commencement of the process to appoint a new full-time Chief Executive Officer ('CEO'); and
 - The intention of Mr Otto Buttula to relinquish executive duties, following a handover period, post the appointment of the new CEO.
- On 14 December 2023, the Company advised that Mr James Barrie would be appointed Joint Company Secretary of the Company, effective 1 January 2024. Mr Barrie is a professional Company Secretary and Director, and the Board welcomes his assistance moving forward. Ms Andrea Steele will continue in her role as Joint Company Secretary and General Counsel of RHY and work with Mr Barrie to ensure a smooth transition into the role. For the purposes of ASX Listing Rule 12.6, Mr Barrie will be the person responsible for communications with the ASX in relation to ASX Listing Rule matters.
- On 14 December 2023, a 603 Form notice alerted the Company to a new Notice of initial substantial shareholder, comprising 3 parties together (Daniel Eddington and Julie Eddington as trustee for DJ Holdings Trust (Eddington Parties); JAWAF Enterprises Pty Ltd ACN 607 150 130 as trustee for Hall Family Trust, Julia Hall and Anthony Hall (Hall Parties); and Loumea Investments Pty Ltd ACN 618 379 329 and Richard Vom (Vom Parties). Despite significant discussions, on 14 December 2023, these 3 parties together lodged a s249D notice, requesting an Extraordinary General Meeting (EGM) to remove Mr Otto Buttula as a director of the Company.
- On 29 December 2023, the Company announced the resignation of Dr Rachel David as a Non-Executive Director of the Company given extracurricular events of recent times and other corporate roles and responsibilities. It should be noted Dr David, retains a demanding full-time executive position, as Chief Executive Officer of Private Healthcare Australia.
- Cash at bank at the end of the quarter was ~\$1.22m.

Subsequent to Period-End

EGM

- On 4 January 2024, the Company released its EGM - Notice of Meeting booklet to be sent to all shareholders, pertaining to the EGM to be held on 12 February 2024.
- The booklet contains a statement by the Company's Non-Executive Directors unanimously supporting the position of Mr Otto Buttula, as an ongoing Director and Chairman of the Company, in addition to a statement by the Requisitioning shareholders. The Board maintains its unanimous position for shareholders to vote '**AGAINST**' the resolution brought by the Requisitioning shareholders and have voted all their shares accordingly.

- Hence the Board reiterates their recommendation that all shareholders vote **'AGAINST'** the resolution to remove Mr Otto Buttula as a director of the Company.

R&D Tax Incentive

- The Company with its professional advisers is in the process of resubmitting a portion of its' R&D Tax Incentive claim for overseas activities, given the reclassification of current product inventories to research use only ('RUO'). The outcome of this claim will be advised upon determination.

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

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

- Finalise Automation Project with Nutripath – **COMPLETED**
- Research & Development Tax Incentive – **1ST TRANCHE RECEIVED, SUBMISSION OF OVERSEAS ACTIVITIES UNDERWAY, GIVEN RECLASSIFICATION OF COLOSTAT[®] KITS TO RUO**
- Commercialisation / partnering agreements with third parties – **DEFERRED – AS A RESULT OF THE COLOSTAT[®] RE-DESIGN, THOUGH DISCUSSIONS CONTINUE**
- Progression of the Company's technology platform expansion program – **INITIAL OUTCOMES RELEASED ON BREAST & LUNG CANCER SCREENING COMPLETED**
- Submit ColoSTAT[®] publication - **COMPLETED**
- Resubmission plan for ColoSTAT[®], incorporating IVDR standards both within Australia and the EU – **SYNOPSIS RELEASED AND ACTIVITIES UNDERWAY**
- Further progress with validation centre project rollout in the UK - **DEFERRED – GIVEN COLOSTAT[®] RE-DESIGN, NEXT MEETING SET FOR 4Q'FY24**

Matters we expect to deliver upon in 2HFY'24, include:

- Appointment of a suitably qualified CEO;
- ISO Audit;
- Progress updates from our U.S. based CMO on ColoSTAT[®];
- New patent applications lodgement, extending the duration for ColoSTAT[®] protection in a broader set of jurisdictions; and
- Establishment of ColoSTAT[®] Medical Advisory Committee.

- ENDS -

Authorised for release by the Board.

For further information contact:

Mr Otto Buttula
Executive Chairman

Ms Elena Deak
Chief Commercial Officer

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 DECEMBER 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,324)	(2,489)
(b) product manufacturing and operating costs		(1,168)
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(258)	(372)
(f) administration and corporate costs	(420)	(747)
1.3 Dividends received (see note 3)		
1.4 Interest received	11	38
1.5 Interest and other costs of finance paid	(1)	(2)
1.6 Income taxes paid		
1.7 Government grants and tax incentives	1,690	1,690
1.8 Other		
1.9 Net cash from / (used in) operating activities	(302)	(3,050)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(1)	(80)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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	(1)	(80)

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		270
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(23)	(46)
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	(23)	224

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,544	4,124
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(302)	(3,050)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1)	(80)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(23)	224
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	1,218	1,218

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	1,218	1,544
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)	1,218	1,544

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	128
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>		

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)	(302)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,218
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,218
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.03
<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: 31 JANUARY 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.