ASX Announcement

24 October 2024

Rhythm Biosciences Quarterly Report – September 2024

Highlights

- ✓ **Significant progress achieved in 2nd Generation ColoSTAT® Multiplex *Alpha* Kit, with superior analytical results compared to the 1st Generation Kit;**
- ✓ **Positive progress in platform expansion activities, with comprehensive analytical data identifying informative subsets of gastric cancer protein biomarkers with potential to be developed into a gastric cancer clinical diagnostic assay;**
- ✓ **Board Renewal Process commenced, with Dr David Atkins, our Chief Executive Officer (CEO), joining the Board as Managing Director (MD); and**
- ✓ **Research & Development Tax Incentive (RDTI) Submissions for both 2023 and 2024 now submitted, with substantial cash inflows expected prior to calendar year end.**

Subsequent to Period End

- ✓ **Board approves management recommendation to pursue Lung Cancer as next portfolio expansion diagnostic.**

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 September 2024. This report includes ongoing Company development activities aimed at progressing the development and commercialisation of ColoSTAT® (2nd Generation), 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.

Product Development and Manufacturing

The Company was in receipt of the first batch of *Alpha* kits of the next generation ColoSTAT and successfully completed performance verification using synthetic targets. Furthermore, the Company is pleased to report that completion of its preliminary testing results using patient samples (including a novel custom algorithm) revealed **superior analytical results from the ColoSTAT® 2nd generation (multiplexed) Kits**, compared to those previously reported for the first-generation product.

The tests were conducted upon 200 previously collected patient serum samples (100 from cancer patients and 100 controls) to generate new assay data using the *Alpha* kits. A subset of this data was used to create a new prototype algorithm designed to separate cancer from non-cancer samples. The performance of the new, 2nd generation ColoSTAT® kit surpassed the target of equivalence to the first-generation kit, encouragingly displaying **superior performance** characteristics.

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® 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® could be used to rank symptomatic patients based on their individual cancer risk to inform triage or prioritisation of the highest risk patients for colonoscopy first. While general population screening is still a Company priority, an intermediate commercial application in the triage market could represent an attractive intermediate market opportunity. The Company has engaged an experienced, global market research consultancy to complete a deeper analysis of this clinical and commercial opportunity in Australia. Furthermore, independent consultants have been engaged in the UK and USA to complete similar analyses and begin to establish commercial partnerships.

Platform Expansion

The Company previously reported on plans to expand the cancer diagnostic "menu" that it can support beyond ColoSTAT® and colorectal cancer. In this work the Company has collaborated with partners Agilex Biolabs, the Baker Institute and Nexomics (via Peter MacCallum Cancer Centre). Results have been presented for lung and breast cancer and analysis of results for gastric cancer have now been completed. A case/control study was performed to assess the feasibility of identifying combinations of blood protein biomarkers capable of discriminating between blood samples from patients with gastric cancer and those of healthy controls. Univariate and multivariate analysis was completed, and this preliminary R&D identified promising combinations of 6 protein biomarkers that can distinguish between patients with and without gastric cancer with sensitivities > 75% at a specificity of >90%.

Subsequent to period-end, the Board approved management's recommendation to advance lung cancer diagnostics as the next candidate assay for entry into the development pipeline.

Corporate

Board Renewal Process

New Addition – Having added strong operational value to the business since commencement, in addition to successfully having completed his probationary status, the Board welcomed Dr David Atkins to the Board as Managing Director.

Retirements - Dr Trevor Lockett and Mr Lou Panaccio, both of whom have been directors since before the Company's ASX listing and having served in excess of 7 (seven) years on the Board will, in the interests of renewal, retire from the Board effective 20 November 2024, the day of the Company's AGM.

Stepping Down - Mr Otto Buttula has also expressed a desire to step down from the position of Chair after having served in excess of 5 (five) years in the position and this will be effective upon the appointment of a new Board Member and Chair.

R&D Tax Incentive (RDTI) – Following consultations with its Tax Advisers and auditors, the Company submitted final RDTI returns for **financial years ending 2023 and 2024, with substantial cash inflows**

expected prior to calendar year end. In order to meet ongoing interim requirements, the Company has established a Financing Facility with an external and independent lender, secured against current and future RDTI refunds.

Review of Prior (before end of CY'24) Stated Value Inflection Points

- ✓ RDTI Submissions completed for 2023 (update) and 2024 (new);
- ✓ Delivery of newly designed ***Alpha*** 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 from an initial cohort of 600 patient samples; and
- ✓ Finalisation of the triage application market access strategy for the next generation ColoSTAT® assay.

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

- ✓ Receipt of RDTI returns;
- ✓ Delivery of verified ***Beta*** versions of newly designed multiplex kits to our Australian office by Quansys, our US-based CMO; and
- ✓ Market-entry roadmap for the colonoscopy triage application for the next generation ColoSTAT® assay.

- ENDS -

Authorised for release by the Board.
For further information contact us via investor@rhythmbio.com:

Dr David Atkins Managing Director and Chief Executive Officer	**Mr Guy Carisbrooke** 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 X.

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	30 SEPTEMBER 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(638)	(638)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs (not included above)	(181)	(181)
	(f) administration and corporate costs	(248)	(248)
1.3	Dividends received (see note 3)		
1.4	Interest received	4	4
1.5	Interest and other costs of finance paid	(6)	(6)
1.6	Income taxes paid		
1.7	Government grants and tax incentives		
1.8	Other – insurance prepayment		
1.9	**Net cash from / (used in) operating activities**	**(1,069)**	**(1,069)**

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		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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 – rent deposit	(40)	(40)
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**	**(40)**	**(40)**

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		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings	1,150	1,150
3.6	Repayment of borrowings	(18)	(18)
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**	**1,132**	**1,132**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	709	709
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,069)	(1,069)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(40)	(40)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,132	1,132
4.5	Effect of movement in exchange rates on cash held		
4.6	**Cash and cash equivalents at end of period**	**732**	**732**

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	732	709
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)**	**732**	**709**

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	76
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 amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	1,150	1,150
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**	1,150	1,150

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.

On 14 August 2024, the Company announced on the ASX it entered into a secured loan facility agreement (Loan) with Endpoints Capital Pty Ltd to provide early access to $1,150,000 cash of its forecast ~$1,500,000 FY24 R&D Tax Incentive (RDTI Rebate) expected to be received in full by November 2024.

The Loan is secured by and repayable out of the FY24 RDTI Rebate and attracts a fixed 1.33% per month interest rate. It matures on 31 December 2024, however, can be extended by agreement between the lender and Rhythm. This Loan is being used in a bridging period prior to receiving the FY24 RDTI Rebate, along with the amended FY23 RDTI rebate for overseas activities.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,069)
8.2	Cash and cash equivalents at quarter end (item 4.6)	732
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	732
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.68

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 cash flows will be similar for the foreseeable future given a continuation of the Company's current activities. In addition, the Company anticipates multiple inflows of cash from R&D Incentive claim lodgements (3) within the next quarter.

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 has a proven track record of raising funds as and when needed. Furthermore, the Company has secured a finance facility with an external, independent lender, guaranteed against lodged R&D Tax Incentive refunds to be received by the Company. 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 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: .....24 OCTOBER 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.