

Rhythm Biosciences Quarterly Report - December 2021

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 period ending 31 December 2021. This report includes ongoing company development activities including progress towards the commercialisation of ColoSTAT®, its simple blood test for the detection of colorectal cancer, aimed at global mass market screening.

Commercialisation

- **Regulatory approvals for Europe (CE Mark)**
 - ✓ CE Mark granted allowing ColoSTAT® to be marketed and sold within the European Economic Area (EEA); and
 - ✓ European markets offer a significant addressable market of 231 million people, valued at ~US\$12 billion.

Core Technology

- **Technical Validation**
 - ✓ Ongoing testing of commercially manufactured ColoSTAT® test-kits continued to confirm highly accurate, consistent and reproducible results, equivalent to the exceptional Study 6 outcomes of 84% Sensitivity and 95% Specificity; and
 - ✓ Ongoing laboratory testing further confirms ColoSTAT® significantly outperforms the current market standard testing regime, by as much as 33%, demonstrating high confidence in the potential for positive market acceptance.
- **Platform Technology Expansion**
 - ✓ A platform expansion program identified a number of additional cancer target markets that will form part of a new Research and Development program designed to follow a similar commercial pathway to ColoSTAT®;
 - ✓ The expansion program is expected to be significantly shortened, leveraging the Company's lead biomarker which exhibits pan-cancerous properties; and
 - ✓ The initial five additional cancers to be targeted include:
 - Breast;
 - Cervical;
 - Lung;
 - Gastric; and
 - Pancreatic.

Directors

COVID-19 Update

- ✓ No material change to previous updates. The Company continues to actively manage the ongoing delays and significant impacts to the international supply chains and sourcing of raw materials as it relates to our production and supply and is working with its suppliers to reduce its effect where practicable.

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 2021, pertain to payments to directors for fees, salary and superannuation.

Corporate

- ✓ Cash at bank at the end of the Quarter was \$5.5 million, excluding a Placement for \$6.5 million (before costs) completed in January 2022;
- ✓ Received \$2.4 million from the Company's R&D Tax Incentive claim for FY'21;
- ✓ The Australian government's R&D tax incentive encourages companies to engage in R&D programs by providing a refundable tax offset of up to 43.5% for eligible activities;
- ✓ General Meeting of shareholders was held on 24 November 2021 with all resolutions passing; and
- ✓ Board and management structure was strengthened and re-aligned to focus on commercialisation scale up activities, which included:
 - The appointment of Dr Rachel David, an experienced senior health and financial services sector executive, as an independent Non-Executive Director;
 - Otto Buttula transitioned from Non-Executive to Executive Chairman; and
 - Chief Executive Officer, Glenn Gilbert was appointed to the Board as Managing Director.

Subsequent to period end:

- ✓ Completed a \$6.53 million exclusive Placement to a single global institutional fund manager, extending a cash runway into late 2023, excluding any expected commercial revenues; and
- ✓ CE Mark certification for ColoSTAT[®] has now been extended to include Great Britain (England, Wales, Scotland) and Northern Ireland.

Review of Prior (Q3FY'21) Stated Value Inflection Points

- ✓ CE Mark submission and approval in late 2021 – **ACHIEVED**
- ✓ Progress R&D platform technology opportunities – **COMMENCED**
- ✓ Progress and finalise regulatory requirements for TGA submission – **COMMENCED & ON TRACK**
- ✓ Confirm commercialisation pathways – **COMMENCED & ON TRACK**

Future Value Inflection Points

Matters we expect to deliver upon in the next two quarters include:

- Advance R&D platform technology expansion program;
- Complete remaining clinical trial requirements;
- Complete and finalise regulatory requirements for TGA submission; and
- Progress commercialisation and partnering discussions with third parties.

- ENDS -

Authorised for release by the Board.

For further information contact:

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About Rhythm Biosciences

Rhythm Biosciences is focused on becoming a globally significant, transformative, predictive diagnostics company, specialising in cancer detection technology. The Company is currently developing ColoSTAT[®] - a simple, low-cost, blood test for global mass market detection of colorectal cancer.

Worldwide, colorectal cancer is the third most common cancer in men and the second most common in women, accounting for an estimated 1.9 million new cases and 935,000 deaths annually.

In an effort to reduce the global burden, many countries have implemented screening programs aimed at early detection. These programs are predominantly administered with a faecal immunochemical test (FIT) for the assessment of colorectal cancer risk, with a positive result referred for a colonoscopy. FIT only analyses the presence of blood in faeces, which can occur for several reasons other than cancer, therefore it is not designed as an accurate test for cancer. Many people simply don't take the test for fear of an unnecessary colonoscopy procedure, unpleasantness, difficulty, or for religious/cultural reasons. There is currently no appropriate blood test alternative.

Rhythm aims to transform the global mass-market for colorectal cancer detection with ColoSTAT[®] its simple, low-cost blood test that is fit for purpose, meaning that it is designed to actually detect colorectal cancer. Since listing on the ASX in 2017, the Company has run a successful multi-year research and development program that has delivered technical validation of the core biomarker technology, being reproducible and stable. The ColoSTAT[®] test-kit was manufactured in 2021 and delivered performance testing that outperforms the current market standard faecal immunochemical test (FIT) utilising Rhythm's proprietary algorithm. The Company is currently finalising its clinical trial for ColoSTAT[®], and is progressing regulatory, manufacturing and scale up activities ahead of market entry in 2022.

ColoSTAT[®] is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT[®] has the potential to play a key role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Rhythm's initial targeted global addressable population is over 800 million people which are over 50 years of age. Almost 70%, or 550 million people, are not currently screened for colorectal cancer due to the limitations of the current faecal based testing regime. This "at risk" population is also expanding with the disease growing rapidly in much younger age groups. Early detection and intervention can lead to cure in over 90 per cent of new cases, therefore the need for effective screening and early intervention has the potential to save a significant number of lives. Rhythm estimates today's colorectal cancer screening market alone to be worth in excess of \$38 billion.

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 2021

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	(1,803)	(3,809)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(99)	(226)
(f) administration and corporate costs	(281)	(527)
1.3 Dividends received (see note 3)		
1.4 Interest received	5	6
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives (R&D)	2,412	2,412
1.8 Other		
1.9 Net cash from / (used in) operating activities	234	(2,144)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment		(13)
(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		(13)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		5,571
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	100	115
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(72)	(215)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		
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	28	5,471

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,280	2,228
4.2	Net cash from / (used in) operating activities (item 1.9 above)	234	(2,144)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		(13)

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)	28	5,471
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	5,542	5,542

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	5,542	5,280
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	5,542	5,280

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	77
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 consulting services.</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 <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)	234
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,542
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,542
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	23.7
<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: ...27 January 2022.....

Authorised by: ...with the authority of 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.