

Rhythm Biosciences Quarterly Report – June 2022

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 30 June 2022. The predominant activities during the period relate to activities focussed upon the commercialisation of ColoSTAT[®], Rhythm's simple blood test for the detection of colorectal cancer, aimed at global mass market screening. In addition, the Company has begun leveraging its existing technologies and progressing a pipeline of multiple cancer diagnostic initiatives.

Commercialisation

- ✓ **Final Therapeutic Goods Administration (TGA) Submission Step Completed to Achieve Approval for ColoSTAT[®] for sale in the Australian market:**
 - ✓ Rhythm successfully filed regulatory documentation for ColoSTAT[®] to be listed on the Australian Register of Therapeutic Goods (ARTG);
 - ✓ The period encompassed completion of the final step of a two-step submission process, with the TGA now actively assessing Rhythm's ARTG listing submission; and
 - ✓ The Company anticipates the TGA review process for a final approval decision to be completed within 6 months from submission (ASX announcement 12 May 2022).
- ✓ **ColoSTAT[®] market release activities in train**

The Company is currently focused on executing across a number of key technical, administrative, supply and logistical activities that will support the pathway to market entry for ColoSTAT[®] in late CY'22, particularly internationally (but also domestically), including:

 - ✓ Completion of the final clinical study report;
 - ✓ Partnering / commercialisation deals (International and domestic); and
 - ✓ International country submissions / registration updates.

Core Technology

- ✓ **Clinical Trial (Study 7) Completed**
 - ✓ Primary and Secondary Endpoints of the clinical trial were successfully achieved;
 - ✓ Outcome confirms statistically significant and outstanding performance for ColoSTAT[®], recording:
 - ✓ 81% Sensitivity¹ and a Specificity² of 91%;
 - ✓ Performance that demonstrates ColoSTAT[®] to be 35% more accurate than the market standard Faecal Immunochemical Test (FIT) for detecting cancer; and
 - ✓ Higher accuracy than the market standard FIT for detecting advanced adenomas.
- ✓ **Final Clinical Trial Site Now Closed**

¹ **Sensitivity** is the ability of the test to correctly identify those patients with colorectal cancer, that is, the percentage of people with colorectal cancer who are correctly identified as having illness.

² **Specificity** is the ability of the test to correctly identify people who do not have colorectal cancer, that is, the percentage of people without colorectal cancer who are correctly identified as not having cancer.

- ✓ Closure of all ColoSTAT® clinical trial sites following the successful achievement of all required paperwork signoffs, signifies the completion of operational aspects and confidence by the Company that all compliance measures have been met for regulatory submission.

COVID-19 Update

- ✓ No material change to previous updates. The Company continues to actively manage the ongoing delays and impacts to international supply chains and the 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 30 June 2022, pertain to payments to directors for fees, salary and superannuation.

Corporate

- ✓ Cash at bank at the end of the Quarter was \$7.6M; and
- ✓ Effectively all clinical trial (Study 7) spend has been incurred, only minor administration tasks remain.

Further funds are expected to be received before the calendar year end, as a result of:

- ✓ 3,191,285 remaining 'in the money' \$1.20 exercisable Options, expiring 31 August 2022, raising ~\$3.8M; and
- ✓ FY'22 R&D tax incentive refund is expected to be in excess of FY'21's \$2.4M received, due to the increased FY'22 expenditure involved in Study 7.

Subsequent to period end:

- ✓ Rhythm completed its initial biomarker review to support platform expansion of its core cancer detection technology. Further, the leading biomarkers have now been identified - critical to progress research and development into each other target cancers: Breast, Lung, Cervical, Pancreatic and Gastric.
- ✓ In parallel, the Company appointed its first bioanalytical partner, Agilex Biolabs, engaged to accelerate the development program.

Review of Prior (Q4FY'22) Stated Value Inflection Points

- ✓ Commence R&D platform technology expansion program in at least two of the identified further cancers targets – **COMMENCED & ONGOING**
- ✓ Complete clinical trial (Study 7) submission requirements – **ACHIEVED & COMPLETED**
- ✓ Submit Therapeutic Goods Administration (TGA) regulatory application – **ACHIEVED & COMPLETED**
- ✓ Enter into commercialisation and / or agency / partnering agreements with third parties – **ACTIVELY ENGAGED**
- ✓ File international country submissions / provide regulatory updates – **COMMENCED & ONGOING**

Future Value Inflection Points

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

- Progress R&D platform technology expansion program in at least two of the identified further cancers targets;
- Enter into commercialisation and / or agency / partnering agreements with third parties;
- Work constructively with the Therapeutic Goods Administration (TGA), responding within allocated timeframes, in conjunction with our experienced, third-party consultants; and
- File additional international country submissions / provide regulatory updates.

- 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")

30 JUNE 2022

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	(1,976)	(7,264)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(140)	(508)
(f) administration and corporate costs	(288)	(1,183)
1.3 Dividends received (see note 3)		
1.4 Interest received	12	25
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives (R&D)		2,429
1.8 Other		
1.9 Net cash from / (used in) operating activities	(2,392)	(6,501)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(7)	(22)
(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	(7)	(22)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		12,104
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	3	217
3.4	Transaction costs related to issues of equity securities or convertible debt securities		(476)
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	3	11,845

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	9,946	2,228
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,392)	(6,501)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(22)

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)	3	11,845
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	7,550	7,550

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	7,550	9,946
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)	7,550	9,946

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	198
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)	(2,392)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,550
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,550
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.16
<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:29 July 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.