

## Rhythm Biosciences Quarterly Report - September 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 30 September 2021. Satisfyingly, the Company continues to make meaningful progress towards the commercialisation of ColoSTAT<sup>®</sup>, its simple, low-cost blood test for the early detection of colorectal cancer, aimed at global mass market screening.

### Commercialisation

- **USA Market Entry**
  - ✓ Rhythm established a 100% owned US domiciled entity, IchorDX, Inc., which provides optionality and a visible commercial pathway for ColoSTAT<sup>®</sup> in one of the world's largest diagnostic markets; and
  - ✓ Initial US Board appointed, and discussions with US based advisors ongoing.
- **Regulatory approvals for Europe (CE Mark) and Australia (TGA)**
  - ✓ CE Mark application for European approval remains on track for completion by end CY'2021;
  - ✓ Rhythm successfully submitted the first of two key steps for Therapeutic Goods Administration (TGA) approval, with its Manufacturers Evidence documentation accepted by the TGA; and
  - ✓ The remaining step, expected to be completed by 2H'FY'2022, is an Australian Register of Therapeutic Goods (ARTG) listing, which contains further comprehensive documentation such as the product technical files and clinical evaluation reports.

### Clinical Trial – Study 7

- ✓ Significant milestone achieved during the quarter with the completion of the patient recruitment phase for ColoSTAT<sup>®</sup> clinical trial (Study 7);
- ✓ A total of 815 people were recruited from 11 clinical trial sites; Processes have commenced to rapidly move to the next phase including closure of trial sites, testing of samples, statistical analysis and compose a final Clinical Study Report; and
- ✓ Importantly, completion of the recruitment phase moves Rhythm past the increased, variable cost phase.

### COVID-19 Update

- ✓ The Company continues to 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 impact where practicable.

**Rhythm Biosciences Ltd**  
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ASX: RHY

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#### Directors

Otto Buttula	Chairman
Trevor Lockett	Executive Director
Louis Panaccio	Non-Executive Director
Eduardo Vom	Non-Executive Director

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

## Corporate

- ✓ Strongly supported (and heavily oversubscribed) shareholder led capital raising was successfully completed for \$5.571M (before costs), including:
  - Rights issue offer raising the intended \$4.296M; and
  - Additional placement of \$1.275M with sophisticated and other exempt investors.
- ✓ Cash at bank at the end of the Quarter was \$5.280M, excluding R&D refund of \$2.412M;
- ✓ Rhythm is well funded to execute its development and commercial plans outlined in the FY'22 strategic plan;
- ✓ A reduction in variable costs is expected over the remainder of FY'22, given the completion of Study 7 recruitment (subject to no major new initiatives being undertaken); and
- ✓ 2021 Annual General Meeting (AGM) is scheduled to be held Wednesday 24 November at 11:00am (AEDT).

## Subsequent to period end:

- ✓ Rhythm received a \$2.412M R&D tax incentive, which was a ~118% increase compared to the prior year, reflecting the scaled-up research and development, manufacturing and particularly clinical trial activities for ColoSTAT<sup>®</sup>; and
- ✓ Testing on commercially manufactured ColoSTAT<sup>®</sup> test kits confirmed equivalent test results with previously inhouse developed laboratory kits. This is an outstanding result, given most commercially developed kits have a lower accuracy than inhouse lab kits. Testing substantiated successful completion of Study 6 in March 2021, again demonstrating a 33% higher accuracy than the current market standard Faecal Immunochemical Test (FIT) used globally. Consistent and reproducible results, equivalent to the exceptional Study 6 outcomes of 84% Sensitivity and 95% Specificity (refer 16 March 2021 ASX Announcement), have been observed which provide high confidence in Rhythm's cancer diagnostics technology.

## **Review of Prior (Q4FY'21) Stated Value Inflection Points**

- ✓ Outline USA market entry strategy – **ACHIEVED.**
- ✓ Finalise European/Australian regulatory submission pathway – **ACHIEVED.**
- ✓ Commence Platform technology opportunities – **ACHIEVED.**
- ✓ Completion of Clinical Trial (Study 7) recruitment – **ACHIEVED.**

## **Future Value Inflection Points**

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

- CE Mark submission and approval in late 2021;
- Progress R&D platform technology opportunities;
- Progress and finalise regulatory requirements for TGA submission; and
- Confirm commercialisation pathways for ColoSTAT<sup>®</sup> in various jurisdictions.

**- ENDS -**

**Authorised for release by the Board.**

### **For further information contact:**

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Chief Executive Officer  
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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<sup>®</sup> - 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, and is progressing regulatory, manufacturing and scale up activities ahead of market entry in 2022.

ColoSTAT<sup>®</sup> is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT<sup>®</sup> 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 SEPTEMBER 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(2,006)	(2,006)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(127)	(127)
(f) administration and corporate costs	(246)	(246)
1.3 Dividends received (see note 3)		
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives		
1.8 Other		
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,378)</b>	<b>(2,378)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(13)	(13)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
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)		
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(13)</b>	<b>(13)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5,571	5,571
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	15	15
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(143)	(143)
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)		
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>5,443</b>	<b>5,443</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	2,228	2,228
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,378)	(2,378)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(13)	(13)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	5,443	5,443
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>5,280</b>	<b>5,280</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	5,280	2,228
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (provide details)		
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>5,280</b>	<b>2,228</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	71
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>		

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<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 <b>Total financing facilities</b>		
7.5 <b>Unused financing facilities available at quarter end</b>		
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.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,378)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,280
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	* 5,280
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	* 2.22
*As referred to in the activities report the Company received a further \$2.412m R&D Tax Incentive refunds that is <b>not</b> included calculation above.	
<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

*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: ...29 October 2021.....



Authorised by: .....  
Glenn Gilbert - CEO  
(with authority of the Board)

## 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.