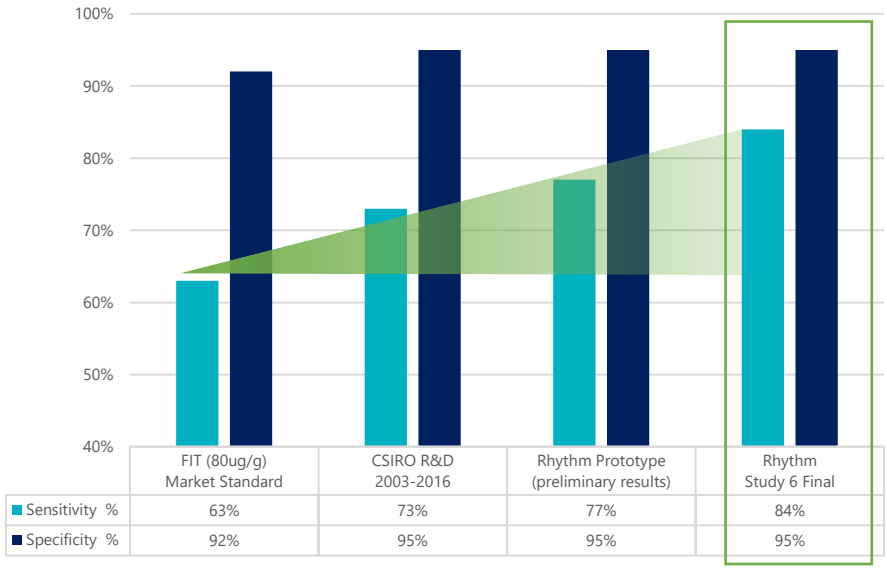
ASX Announcement
ASX: RHY

Rhythm Biosciences Quarterly Report - March 2021

27 April 2021, Melbourne: For the quarter ended 31 March 2021, transformative medical diagnostics company, Rhythm Biosciences Ltd (ASX: RHY) (Rhythm or the Company), continued to meaningfully progress the intended commercialisation of ColoSTAT®, its simple blood test for the detection of colorectal cancer, aimed at global mass market screening.

Core Technology

- Rhythm confirmed the successful finalisation of Study 6 with exceptional results. Study 6 represents the analytical performance of the ColoSTAT® prototype test-kit on actual patient blood samples, in both cancerous and healthy scenarios.
- Study 6 also confirmed that the third-party commercially manufactured ColoSTAT® prototype test-kit exhibited extremely high accuracy for the detection of colorectal cancer via a simple blood test.
- The increase in performance over Rhythm's earlier testing results announced in November 2020, were largely achieved due to continued improvements in Rhythm's proprietary algorithm.
- The test was run across all genders and clearly distinguished between cancerous and healthy blood samples at a sensitivity[1] of 84% and a specificity[2] of 95%, surpassing all prior test results.



	FIT (80ug/g) Market Standard	CSIRO R&D 2003-2016	Rhythm Prototype (preliminary results)	Rhythm Study 6 Final
Sensitivity %	63%	73%	77%	84%
Specificity %	92%	95%	95%	95%

Figure 1: Summary of ColoSTAT® prototype test-kit performance – Study 6 vs previous test work, and the current market standard faecal immunochemical test (FIT)

[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.

Commercialisation - Global Opportunity

- Initial manufacturing of ColoSTAT® prototype test-kits was completed by Rhythm's global manufacturer, Biotem, based in France.
- The US is currently leading the call to address the growing burden of colorectal cancer by increasing the number of people being screened, with the US Preventative Services Task Force recommending the screening age be reduced from 50 to 45 years. This would increase the targeted screening population in the US by in excess of 21% to ~114 million people, up from 94 million.
- The lower screening age is expected to occur in all major global markets, substantially increasing the size of the potential screening market. This is particularly important given ~10% of Australians diagnosed with colon cancer are under the age of 50.
- The US Centers for Medicare and Medicaid Services released a draft decision outlining the criteria for the reimbursement of current and future blood-based colorectal cancer screening tests, which included:
    - the requirements for the patient being age 50 or over, asymptomatic, and without known risk factors such as family history of colorectal cancer (CRC) or its precursors;
    - tests must demonstrate both **sensitivity greater than or equal to 74 percent and specificity greater than or equal to 90 percent;** and
    - ColoSTAT® **would meet the requirements for reimbursement eligibility in the US based on the Study 6 performance of 84% sensitivity and 95% specificity.**

Clinical Trial – Study 7

- In February, the Company progressed its ColoSTAT® Clinical Trial (Study 7), confirming that a tenth clinical trial site was operational, with the appointment of Sunshine Coast University Hospital, the first trial site in Queensland. The hospital is a major provider of public health services and research in the Sunshine Coast, Gympie and Noosa local government areas, and includes a dedicated centre for clinical research which is resourced with gastroenterology nurses as study co-ordinators to facilitate recruitment. The Principal Investigator, Dr Andrew Sloss, is a gastroenterologist and senior lecturer at the University of Queensland.
- Subsequent to period end, Rhythm further extended the geographic diversification of its clinical trial with the Company announcing that CliniTrials, a six-site network of clinicians with centralised administration in Western Australia appointed as the latest group to join Rhythm's clinical trial for ColoSTAT®. With over 20 years of experience, CliniTrials catchment area includes large patient populations across Perth, Mandurah and the Busselton regions. Clinicians at the GP and family practice level are intimately connected with their patients at these locations and are well placed to identify those people that could participate in the trial.
- As part of the ongoing management of the clinical trial process, Rhythm also made changes to the administration of the trial including the withdrawal of Adelaide based clinical trial site, Lyell McEwin Hospital, due to changes with their governance systems, processes and staffing. Responsibilities relating to ethics and administrative purposes were subsequently transferred to Concord Repatriation General Hospital.

Quality

- The Company maintained its certification to the International Standard for In-Vitro Diagnostics and Medical Devices (ISO13485:2016), having passed an audit conducted by the British Standards Institution (BSI).
- This marks the third year running that Rhythm has achieved and maintained certification with the ISO standard. This achievement is critically important as it supports the Company's intention to pursue regulatory approvals as part of its commercial and market entry strategy.
- ISO13485 is the internationally recognised quality standard to ensure the consistent design, development, production, installation and sale of medical devices that are safe for their intended purposes. Compliance to the standard is audited annually.

COVID-19 Update

- No Material Change to the Previous Update. The Company continues to actively manage against any delays and impacts to the international supply chains and sourcing of raw materials as it relates to production and supply.
- Rhythm continues to work with its suppliers to reduce any COVID-19 impact.

Related Party Payments

- In line with its obligations under ASX Listing Rules, Rhythm notes that the only payments to related parties of the Company, as advised in the Appendix 4C for the period ended 31 March 2021, pertain to payments to directors for fees, salary and superannuation.

Corporate

- Cash at bank at the end of the Quarter was $4.57m

Review of Prior (Q2FY'21) Stated Value Inflection Points

- ✓ Study 6 completion – **ACHIEVED.**
- ✓ Receipt of further test kits for quality and verification testing - **ACHIEVED.**
- ✓ Confirmation of Sensitivity and Specificity results in a third-party test kit – **ACHIEVED.**
- ✓ Additional trial site recruitment - **ACHIEVED.**
- ❖ Finalise remaining supply agreements – **ON TRACK.**

Future Value Inflection Points

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

- Additional trial site recruitment;
- Finalisation of European and Australian regulatory submission pathways;
- Outline USA & China market entry strategies; and
- Commencement of further platform technology opportunities.

Released with the authority of the Board.

For further information, please contact:

Glenn Gilbert
Chief Executive Officer
+61 3 8256 2880

About Rhythm Biosciences

Rhythm Biosciences (ASX: RHY) is a transformative, predictive diagnostics company, specialising in early cancer detection. Rhythm's initial business pursuit is centred upon technology originally developed by the CSIRO and involves the development and commercialisation of a screening and diagnostic test for the early detection of colorectal cancer, the third biggest cause of cancer-related deaths globally.

Rhythm's lead product, ColoSTAT®, is intended to be a simple, affordable, minimally invasive and effective blood test for the early detection of bowel cancer for the global mass market. It is expected to be comparable to, if not better than, the current standard of care, the faecal immunochemical test (FIT), at a lower cost. ColoSTAT® also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

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 an important role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Globally, over 850,000 people die from colorectal cancer each year. Colorectal cancer is typically diagnosed at a later stage when there is a poor prognosis for long-term survival. Annual estimated unscreened 50-74-year old's is estimated at +130m for the US, EU and AU alone, with this market potential being more than $6.5b.

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	31 MARCH 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(1,172)	(3,225)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs (not included above)	(101)	(342)
	(f) administration and corporate costs	(145)	(545)
1.3	Dividends received (see note 3)		
1.4	Interest received	2	19
1.5	Interest and other costs of finance paid		(2)
1.6	Income taxes paid		
1.7	Government grants and tax incentives		1,109
1.8	Other (COVID-19 Government stimulus)		50
1.9	**Net cash from / (used in) operating activities**	**(1,416)**	**(2,936)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(41)	(61)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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**	**(41)**	**(61)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		6,034
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		(224)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(11)	(61)
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**	**4**	**5,764**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,018	1,798
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,416)	(2,936)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(41)	(61)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4	5,764
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**4,565**	**4,565**

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	2,065	1,518
5.2	Call deposits	2,500	4,500
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)**	**4,565**	**6,018**

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	79
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 consulting services.

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		
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)	(1,416)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,565
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,565
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.2

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: 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: .27 April 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.