ASX Announcement
ASX code: RHY
ACN: 619 459 335

Rhythm Biosciences Quarterly Report December 2019

Quarter Highlights:

- **Biomarker and antibody panel testing continues to progress, building upon the success of our key lead biomarker, along with further antibody combinations;**
- **Extension of China patent provides IP protection to 2031;**
- **AGM held, with all resolutions passed without amendment;**
- **New Chairman, Otto Buttula appointed; and**
- **Strong balance sheet with $3.65 million of cash reserves.**

Subsequent to period-end, Strategy Review commenced upon:

- **The addition of further clinical trial sites (Study 7) to accelerate patient / sample recruitment;**
- **Further augmenting our internal scientific and testing development team, and re-engaging with external development partners;**
- **Selecting a high-volume manufacturing partner; and**
- **Finalising a comprehensive, updated strategic plan to re-energise our commercial aims.**

30 January 2020, Melbourne: For the quarter ended 31 December 2019, medical diagnostics company Rhythm Biosciences Limited (ASX: RHY) continued to progress the development of ColoSTAT®, its global, low-cost, lifesaving blood test for the early detection of colorectal cancer.

After more than a decade of research, CSIRO scientists identified in excess of 68 biomarkers reported to vary in concentration in the blood of patients with and without colorectal cancer. CSIRO then evaluated these biomarkers across multiple studies. The studies found that when certain combinations of these biomarkers are measured in a blood sample, and their concentrations are weighted using an appropriate internally generated algorithm, a relevant and valuable colorectal cancer risk score can be determined.

Rhythm has continued to build upon this research by progressing internal test development, which has been buoyed by the announcement during the previous quarter (19 September 2019) indicating the key lead biomarker antibodies had successfully **shown the ability to differentiate between cancer and healthy samples**. This is a significant step forward, as it now allows Rhythm to focus further on the adjunct biomarker antibodies, that will serve to support the lead biomarker.

This previously announced development represented a crucial step in the progression of completing the ColoSTAT® blood test as this key lead biomarker is known to be the majority contributor of the algorithm that will ultimately generate a colorectal cancer risk score for an individual. Securing the effectiveness of this proportion of the algorithm – which forms the cornerstone of the ColoSTAT® blood test kit – has significantly de-risked Rhythm's technology from a scientific point of view.

To complete the final ColoSTAT® test, Rhythm will prove-up a panel of selected biomarkers from the original CSIRO research. CSIRO had used a combination of individual commercial and 'research use' kits for their studies. As a result of this research, Rhythm are confident of the biomarkers to assess, with the antibodies for the supporting adjunct biomarkers continuing to be finalised. While targeting the same biomarkers as the CSIRO research, Rhythm's ColoSTAT® test will use its own version of antibodies which are intended to be combined in the one final test kit. This enables Rhythm to maintain and generate new intellectual property, potentially improving the performance of the test and providing greater control over the quality, supply and cost of materials. Subsequent to period-end, the company is reviewing the resourcing requirements to expedite this development work.

The clinical trial (Study 7) is currently being conducted at four sites; Adelaide's Lyell McEwin Hospital and three Melbourne hospitals, namely Monash Health, The Alfred Hospital and Royal Melbourne Hospital. Patient recruitment for the trial is ongoing. We note that there was a period of 4 months between the first site signing (Lyell McEwin) and the first Melbourne site (Monash Health). This took longer than anticipated due to ethics and internal hospital governance approval processes, all of which will be reassessed between management, the Contract Research Organisation ('CRO') and existing and envisaged new trial sites.

Rhythm relies heavily on the participating trial sites to identify, recruit and obtain consent from volunteer patients. This includes ensuring patients meet the protocol acceptance criteria, take further details of the participant, including medical history, personal and family colorectal cancer history and other such information. Noting that whilst there are many general colonoscopies conducted for a variety of reasons, the acceptance criteria for the Rhythm clinical trial are specific, and therefore the potential recruitment pool is somewhat limited and requires highly motivated trial sites to prioritise Rhythm's clinical trial against the many other clinical trials that the hospitals have ongoing.

Cognisant of this, Rhythm is assessing the feasibility of adding additional trial sites to accelerate recruitment, whilst also reviewing all aspects of the clinical trial to remove any roadblocks (where practicable) that may hinder recruitment, including the review of trial site recruitment processes. The company will provide regular updates on patient recruitment in ensuing periodic reports.

Following recruitment, the completion of analytical testing and the final clinical trial report will form supporting evidence for ColoSTAT®'s suitability for use in detecting colorectal cancer, which will then underpin applications for a CE mark in the European Union (EU) and Therapeutic Goods Administration (TGA) approval in Australia.

Additionally, during the quarter, Rhythm was granted a divisional patent for ColoSTAT® in China. Granting of the divisional patent expands the combinations of biomarkers that can be used in the ColoSTAT® test kit marketed in China beyond those covered by the original granted Chinese patent. Together, these patents cover Rhythm's preferred sets of biomarker combinations and will provide protection until 2031.

Previously, Rhythm has been granted patents for the diagnosis of colorectal cancer in Australia, China, Europe and Japan, and has patent applications pending in the US, Brazil and India.

Rhythm's immediate focus is to augment its scientific development team in order to better progress the development of the adjunct biomarkers within the ColoSTAT® test kit and to increase patient recruitment for the clinical trial.

As Rhythm moves through the development to appointing a manufacturer and completion of its clinical trial, the company is concurrently working on business development and commercialisation activities including engaging with government, developing partnerships with health insurance companies, global IVD companies and with pathology laboratories.

Whilst in the development phase, it is important to recognise the market potential for ColoSTAT® is significant and worldwide. With each internal test that is performed, Rhythm is gathering further data and greater understanding of our unique test. ColoSTAT®, being a simple blood test, has the potential to be an accurate diagnostic tool that could increase global compliance of participating countries national bowel cancer screening programs, allowing for an uncomplicated widening of potentially screened population ages. In Australia, the national bowel screening program is offered only to those between 50-74 years of age. Initially, we envisage market-entry of ColoSTAT® into these programs, via supplementing the current faecal test (FIT) or to improve triage of those patients booked for colonoscopy. Further, ColoSTAT® has the potential to be referred by doctors as part of both routine (or ad-hoc) annual blood tests they typically refer for their patients, at any age, and should not be limited to any specific laboratory or blood collection centre. ColoSTAT® has the potential to attract reimbursement by both governments and health insurance companies.

Assuming success with the commercial launch of ColoSTAT®, not only could this simple blood test work alongside FIT, but has, subject to the results of post market release data, the potential for ColoSTAT® to eventually replace the FIT in some worldwide jurisdictions. Hence it is expected to have a significant impact clinically, socially and economically around the world.

Rhythm continues its strong financial management, finishing the December 2019 quarter with a cash balance of $3.65 million.

Rhythm will further expand upon its Renewed Strategy Initiatives in the coming Half Year report due next month and further as re-set activities are finalised.

For further information, please contact:

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About Rhythm Biosciences

ASX-listed Rhythm Biosciences is endeavoring to develop and commercialise 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. Globally, over 850,000 people die from colorectal cancer each year.

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 DECEMBER 2019

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	(559)	(1,192)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets	(16)	(32)
	(e) staff costs (not included above)	(129)	(280)
	(f) administration and corporate costs	(93)	(274)
1.3	Dividends received (see note 3)		
1.4	Interest received	18	26
1.5	Interest and other costs of finance paid	(2)	(4)
1.6	Income taxes paid		
1.7	Government grants and tax incentives		744
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(781)**	**(1,012)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		(4)
	(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**		**(4)**

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		
3.6	Repayment of borrowings	(40)	(65)
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**	**(40)**	**(65)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,468	4,728
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(781)	(1,012)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(4)

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)	(40)	(65)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**3,647**	**3,647**

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	632	1,468
5.2	Call deposits	3,015	3,000
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)**	**3,647**	**4,468**

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	58
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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

Payments relate to director fees and salaries.

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	57	57
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**	57	57

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.

Bank of Queensland Insurance loan. Unsecured. Interest rate: 4.99% p.a. Matures on 17/07/2020 with fixed repayments.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(781)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	3,647
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	3,647
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	4.67

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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

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

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

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: .....30 January 2020.....

Authorised by: ....
(Adrien Wing – Company Secretary)

(By 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.