

Rhythm Biosciences Quarterly Report June 2019

HIGHLIGHTS

- **Test development progressing**
- **Royal Melbourne Hospital joins Rhythm's clinical trial (Study 7), with Professor Finlay Macrae site Principal Investigator**
- **Further clinical trial sites selected with Melbourne's Monash Health and The Alfred Hospital having also joined the clinical trial (Study 7)**
- **Rhythm receives ISO certification**
- **Financially strong with \$4.7m cash**

25 July 2019, Melbourne: In the quarter ended 30 June 2019 medical diagnostics company Rhythm Biosciences Limited (ASX: RHY) continued developing its global, low-cost, lifesaving blood test for the detection of colorectal cancer, ColoSTAT®.

TEST DEVELOPMENT

Following 13 years of CSIRO research, Rhythm acquired the IP and technology underpinning the research, using commercially available kits, for the ColoSTAT® test. This involved identifying several biomarkers that have been shown to change in concentration in the presence of colorectal cancer.

Rhythm continue to work with a number of global parties on the most effective test development, optimisation, validation and clinical utility of the reagents that will form the core components to the final ColoSTAT® test.

This work will be verified in a series of confirmatory analytical tests, making up Study 6. The completion of the development, optimisation and validation of these tests will lay the foundation for the final kit development, production transfer, manufacture and sale of ColoSTAT®.

Rhythm is confident that the appropriate antibodies have now been identified along with an informed development pathway for progressing the remaining reagents and test development making up the final commercial ColoSTAT® test. Additionally, Rhythm has identified preferred suppliers, consultants, manufacturers and has established a clear sequence of events to de-risk the science and achieve successful registration.

Rhythm BiosciencesACN: 619 459 335
ASX: RHY**Issued Capital**100,750,000 Shares
3,504,200 Options and
Performance Shares**Australian Registered Office**Level 17, 500 Collins Street
Melbourne VIC 3000
www.rhythmbio.com**Directors**Shane Francis Tanner – Chairman of the Board
Trevor John Lockett – Executive Director
Louis James Panaccio – Non-Executive Director
David John White – Non-Executive Director

The completion of the test optimisation, validation, kit development and transfer to manufacturer program, coupled with the clinical trial analytical results, will form key regulatory components for CE Mark (Europe) and TGA (Australia) for submission in FY21. Rhythm is confident of the technology, the biomarker selection and the work of over 13 years of CSIRO research.

CLINICAL TRIAL

After advising in the previous quarter that Adelaide's Lyell McEwin Hospital would be the first site for the company's proposed 1,000-patient clinical trial (Study 7) of ColoSTAT®, Rhythm announced the second and third trial sites with Melbourne-based public health service provider Monash Health and The Alfred Hospital, both leading Melbourne hospitals.

Rhythm is also pleased to announce that the Royal Melbourne Hospital has come online as the fourth hospital for the clinical trial. Professor Finlay Macrae has been appointed site Principal Investigator.

Professor Macrae is Head, Colorectal Medicine and Genetics at The Royal Melbourne Hospital. Professor Macrae is well recognised locally and internationally for his outstanding contributions to the area of familial cancer screening, surveillance and management. He is Secretary to the International Society of Gastrointestinal Hereditary Tumours (InSiGHT). He is a member of Steering Committee of the US National Institutes of Health Colon Cancer Family Register and Vice Chair of the International CaPP clinical trial group. Professor Macrae has chaired national guidelines and chairs the Australian and New Zealand Gastroenterology International Training Organization.

At Monash Health, the organisation's Head of Clinical Trials, Associate Professor Dr Stephen Pianko, a gastroenterologist, is the site's Principal Investigator for the trial, while at The Alfred, Associate Professor Gregor Brown, the hospital's Head of Endoscopy, fills the equivalent role.

They join Lyell McEwin Hospital's Director of Gastroenterology, Professor Rajvinder Singh, who is the Principal Investigator for that site. Rhythm is both delighted and honoured to have clinicians and researchers of this calibre acting as site principal investigators for the Study 7 clinical trial.

At quarter's end, the first patients for the trial had been recruited by Lyell McEwin Hospital in Adelaide and Monash Health in Melbourne. Rhythm expects the first patients to be enrolled by the Alfred and Royal Melbourne in the coming weeks, ensuring all four trial sites will be up and running.

Rhythm anticipates the recruitment rates to significantly increase over the next two quarters with the recent inclusion of the three large Melbourne hospitals. Rhythm will continue to monitor, in conjunction with its trial partners and advisors, the progression of patient recruitment.

Patient recruitment is on track to be completed in the current financial year.

ISO CERTIFICATION

Rhythm received ISO certification from business standards company British Standards Institution (BSI) Group that the company's Quality Management System (QMS) complies with the International Organization for Standardisation (ISO) EN 13485:2016 standard, which is the internationally recognised quality standard that ensures the consistent design and development, production, storage and distribution of medical devices that are safe for their intended purposes.

Certification under this standard demonstrates compliance with the laws and regulations of the medical device and In Vitro Diagnostic (IVD) industry, enabling Rhythm to be classified as a manufacturer of in vitro diagnostics and medical devices for its own (and licensed) products for worldwide registration and sale. As such, certification represents another major step on the company's path to developing and commercialising the ColoSTAT® screening and diagnostic test.

BUSINESS DEVELOPMENT

The development of the final test kit remains Rhythm's key task. Rhythm also continues to work on identifying key partners for the commercialisation of ColoSTAT® globally. The technology and strategy have been well received by potential partner companies and discussions with several IVD/pharma companies are ongoing. In parallel, the ongoing development of a "go to market" plan has commenced for Australia, identifying critical success factors to be met to ensure maximum uptake and sales of ColoSTAT®. Rhythm is currently establishing relationships with key physicians, government and industry bodies.

Rhythm continues its strong financial management, finishing the quarter with a solid cash balance of \$4.7 million.

For further information, please contact:

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About Rhythm Biosciences

ASX-listed Rhythm Biosciences is developing and commercialising a screening and diagnostic tool 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 report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

RHYTHM BIOSCIENCES LIMITED

ABN

59 619 459 335

Quarter ended ("current quarter")

30 JUNE 2019

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	(525)	(1,893)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(128)	(374)
(f) administration and corporate costs	(258)	(999)
1.3 Dividends received (see note 3)		
1.4 Interest received	30	146
1.5 Interest and other costs of finance paid	(2)	(6)
1.6 Income taxes paid		
1.7 Government grants and tax incentives		284
1.8 Other (provide details if material)		
1.9 Net cash from / (used in) operating activities	(883)	(2,842)

2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(3)	(109)
(b) businesses (see item 10)		
(c) investments		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
	(d) intellectual property		
	(e) other non-current assets		
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment		
	(b) businesses (see item 10)		
	(c) investments		
	(d) intellectual property		
	(e) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other – long term deposit		
2.6	Net cash from / (used in) investing activities	(3)	(109)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares		
3.2	Proceeds from issue of convertible notes		
3.3	Proceeds from exercise of share options		
3.4	Transaction costs related to issues of shares, convertible notes or options		
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings – insurance short term loan	(34)	(101)
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	(34)	(101)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	5,648	7,780
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(883)	(2,842)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(109)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(34)	(101)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	4,728	4,728

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	20
5.2	Call deposits	4,723	5,628
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)	4,728	5,648

6. Payments to directors of the entity and their associates

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

**Current quarter
\$A'000**

96

Director fees and salaries.

7. Payments to related entities of the entity and their associates

- 7.1 Aggregate amount of payments to these parties included in item 1.2
- 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

**Current quarter
\$A'000**

8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities		
8.2 Credit standby arrangements		
8.3 Other (please specify)		
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	577
9.2 Product manufacturing and operating costs	39
9.3 Advertising and marketing	32
9.4 Leased assets	
9.5 Staff costs	339
9.6 Administration and corporate costs	366
9.7 Other (provide details if material)	5
9.8 Total estimated cash outflows	1,358

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity		
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		

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.



Sign here:
(Company secretary)

Date:25 July 2019.....

Print name:Adrien Wing.....

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.