

Rhythm Biosciences Quarterly Report March 2019

30 April 2019, Melbourne: In the quarter ended 31 March 2019 medical diagnostics company Rhythm Biosciences Limited (ASX: RHY) continued its progress in developing its global, low-cost, lifesaving blood test for the detection of colorectal cancer, ColoSTAT®.

Following a successful audit by BSI, Rhythm's Quality Management System will be International Organization of Standardisation (ISO) 13485 compliant by mid-2019, allowing for Rhythm to be classified as a manufacturer for In Vitro Diagnostics and Medical Devices.

ISO 13485:2016 is the internationally-recognized quality standard to ensure the consistent design, development, production, installation and sale of medical devices that are safe for their intended purposes.

Having demonstrated feasibility for the materials and reagents required in the ColoSTAT® test, Rhythm's attention has turned to assay development, optimization and initiating its pivotal clinical trial (Study 7).

The final report of the trial will form a key component for the company's CE Mark application in Europe and Therapeutic Goods Administration (TGA) registration application in Australia. Once approved, this opens the way to marketing of ColoSTAT® in Europe and Australia in 2020.

The stand-out achievements for the last quarter have centered on Rhythm's clinical trial of ColoSTAT®.

Key developments for the quarter include:

- Ethics approval by Central Adelaide Local Health Network's (CALHN) Human Research Ethics Committee (HREC)
- First study site in Adelaide's Lyell McEwin Hospital selected
- Sonic Clinical Trials and Plunkett Consulting Group appointed managing operations and central laboratory services respectively.
- First patient recruited at Lyell McEwin Hospital

The protocol for the trial was approved by the Central Adelaide Local Health Network's (CALHN) Human Research Ethics Committee (HREC) in early February 2019.

The approved study protocol describes a prospective, cross-sectional, multi-centre study to evaluate the diagnostic performance of the ColoSTAT® In Vitro Diagnostic relative to colonoscopy (the primary endpoint of the trial). Secondary endpoints of the study include assessing the ability of

Rhythm Biosciences

ACN: 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

ColoSTAT® to detect advanced adenomas and a comparison of the performance of ColoSTAT® to the currently used Faecal Immunochemical Test (FIT); both relative to colonoscopy.

CALHN HREC's approval of the protocol facilitates the inclusion of additional trial sites in Adelaide and Melbourne as needed and allows for reduced time for the approval process at these additional sites. This approval marked a crucial first step in the company's plans to commercialise ColoSTAT®.

Adelaide's Lyell McEwin hospital's Director of Gastroenterology, Professor Rajvinder Singh, is the principal investigator for this site. Prof Singh is internationally recognised for his ground-breaking work in the areas of advanced endoscopic imaging techniques and endoscopic treatment of pre-malignant and malignant lesions in the gastrointestinal tract. He is a committee member of the American Society of Gastrointestinal Endoscopy's International Initiative, and past Chair of the Australian Gastroenterology Endoscopic Association.

Plunkett Consulting Group is providing clinical study oversight and monitoring services for the trial, Sonic Clinical Trials, a subsidiary of Sonic Healthcare, will provide the central laboratory testing and logistics services.

Lyell McEwin Hospital recruited its first participant for the trial in March, on schedule. Rhythm expects to sign up further hospitals to the ColoSTAT® trial in the coming months and expects to complete the trial Q4 2019.

Rhythm finished the last quarter with a solid cash balance of \$5.6m. On the development front, Rhythm continue to work on assay development and optimization leading towards the verification of the assay's technical performance in Study 6, which is scheduled to be completed in late 2019.

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 colorectal 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. Over 850,000 people die worldwide 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")

31 MARCH 2019

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	(455)	(1,368)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(92)	(246)
(f) administration and corporate costs	(223)	(741)
1.3 Dividends received (see note 3)		
1.4 Interest received	34	116
1.5 Interest and other costs of finance paid	(2)	(4)
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	(738)	(1,959)

2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(7)	(106)
(b) businesses (see item 10)		
(c) investments		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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	(7)	(106)

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	(33)	(67)
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	(33)	(67)

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	6,426	7,780
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(738)	(1,959)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(106)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(33)	(67)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	5,648	5,648

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	20	47
5.2	Call deposits	5,628	6,379
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)	5,648	6,426

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**

85

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	806
9.2 Product manufacturing and operating costs	52
9.3 Advertising and marketing	32
9.4 Leased assets	-
9.5 Staff costs	269
9.6 Administration and corporate costs	206
9.7 Other (provide details if material)	10
9.8 Total estimated cash outflows	1,375

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:30 April 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.