

Rhythm Biosciences moves closer to commercial colorectal blood test after a productive quarter



29 October 2018, Melbourne: Medical diagnostics company Rhythm Biosciences (ASX:RHY) has moved a another step further to commercialising its innovative test kit for colorectal cancer, ColoSTAT®, after achieving yet another critical scientific development milestone in the September quarter.

ColoSTAT® a simple and non-invasive blood test for colorectal cancer, with a strategic objective of offering a lower cost and more effective solution to the current faecal immunochemical test (FIT).

Additionally, the test can be used as a 'triage' tool by clinicians for those who have returned a positive FIT test.

During the quarter Rhythm's collaboration partner CSIRO completed the next phase of a reagent development program, the isolation and characterisation of a key set of antibodies central to the ColoSTAT® test.

This work positions Rhythm to better control the development and manufacture of these reagents, thus lessening the company's reliance on third party providers and manage the quality and cost of reagents in a consistent manner.

With this work completed, the company's next steps are to develop scalable approaches for the manufacture of the key reagents (target proteins and antibodies), to integrate them into a robust, reproducible ColoSTAT® test and to verify test performance in blood samples taken from patients with known colorectal cancer (Study 6), which is on track for completion in 2019.

Critically, however, completion of this work also triggers initiation of the pivotal clinical trial (Study 7) concluding in 2019. A 1000-patient clinical trial, using blood samples drawn prospectively from patients referred to a number of colonoscopy clinics in both Melbourne and Adelaide.

In combination with the technical dossier, the clinical testing results will form key components of European (CE Mark) and local regulatory applications that will pave the way to market entry.

Further developments and summaries for the quarter include:

- R&D program for Reagent Development remain on track for completion in late 2018.
- Both Kit Development and Study 6 activities remain on track for completion in 2019.
- The study 7 (clinical trial) remains on track as is expected to be completed in 2019.
- Rhythm has formally commenced its ISO13485 quality certification and expect to be completed by Q2 2019 following scheduled audits.
- Merchant Group's Merchant Opportunities Fund increasing its stake from 7% to 8.1%.
- The company has moved its office and laboratory to one centralized location in the bio21 Institute, Parkville. The bio21 precinct is fast becoming a hub for both small biotech companies and larger ones such as CSL which house their global R&D functions in the same precinct.
- By 2020 we plan to be seeking marketing approval in UK and Europe, as well as applying to the Therapeutic Goods Administration for inclusion of ColoSTAT® on the Australian Register of Therapeutic Goods.

Given the significant opportunity for the test across wide ranging applications globally, the company is reviewing its commercial pathway to ensure its activities are lined up and complementary to the completion of the key milestones stated above.

While colorectal cancer the second most prevalent cancer in Australia, Europe and the US and the third biggest globally, early detection can lead to cure in up to 90 per cent of cases.

With a healthy cash balance and highly experienced management, Rhythm is well placed in taking the next step to make ColoSTAT® a commercial reality and saving many thousands of lives annually.

The board looks forward to further updating shareholders at its 26 November AGM in Melbourne – the company's first since listing in December last year.

Ends

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About Rhythm Biosciences

ASX-listed Rhythm Biosciences is developing and commercialising a diagnosis 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. It is expected to be comparable to, if not better than, the current standard of care of faecal immunochemical tests (FITs) at a lower cost.

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.

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 SEPTEMBER 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(397)	(397)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(75)	(75)
(f) administration and corporate costs	(370)	(370)
1.3 Dividends received (see note 3)		
1.4 Interest received	49	49
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives		
1.8 Other (provide details if material)		
1.9 Net cash from / (used in) operating activities	(793)	(793)

2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(19)	(19)
(b) businesses (see item 10)		
(c) investments		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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	(19)	(19)

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		
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.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	7,780	7,780
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(793)	(793)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(19)	(19)
4.4	Net cash from / (used in) financing activities (item 3.10 above)		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	6,968	6,968

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	13	780
5.2	Call deposits	6,955	7,000
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)	6,968	7,780

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**

95

0

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	1350
9.2 Product manufacturing and operating costs	45
9.3 Advertising and marketing	42
9.4 Leased assets	
9.5 Staff costs	333
9.6 Administration and corporate costs	195
9.7 Other (provide details if material)	
9.8 Total estimated cash outflows	1,965

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:29 October 2018.....

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.