

Rhythm Biosciences Quarterly Report - June 2020

Quarter Highlights:

- **Successful technical validation of key lead biomarker for ColoSTAT[®], significantly reducing Test Kit development risk;**
- **Retained ISO13485:2016 certification for Rhythm's Quality Management System;**
- **Appointment of Non-Executive Director, Mr Eduardo Vom, an experienced healthcare diagnostics and technology entrepreneur;**
- **Test Kit adjunct biomarkers optimised and now in final phase of technical validation; and**
- **\$1.8 million of cash on hand, at 30 June 2020.**

Subsequent to period-end:

- **Capital Raising for ~\$6 million announced, with majority of new shares being offered to current shareholders, via a 3 for 5 rights issue;**
- **Strong board alignment, with all eligible directors indicating their intention to participate and subscribe for new shares;**
- **Non-Executive Chairman to become a substantial shareholder, subject to shareholder approval; and**
- **Successfully completed 1st tranche Placement of \$0.9 million.**

29 July 2020, Melbourne: For the quarter ended 30 June 2020, transformative medical diagnostics company Rhythm Biosciences Ltd (ASX: RHY) continued the development of ColoSTAT[®], its mass screening, low-cost, lifesaving blood test for the early detection of colorectal cancer aimed at the global market.

Development update

The Rhythm development team has continued working through during the Victoria COVID-19 lockdown. Despite the company having experienced some delays in receiving material the team have made good progress.

Lead Biomarker Development – Successfully Technically Validated

Rhythm's development program focuses on developing the individual biomarkers found in the ColoSTAT[®] Test Kit. On 2 April 2020, the Company announced that it had successfully technically-validated the key lead biomarker antibodies which represents the primary biomarker that can differentiate between cancerous and healthy blood samples. Further, as a part of this testing, it was

Rhythm BiosciencesACN: 619 459 335
ASX: RHY**Issued Capital**100,750,000 Shares
3,000,000 Options**Australian Registered Office**Level 2, 480 Collins Street
Melbourne VIC 3000
www.rhythmbio.com**Directors**Otto Buttula – Chairman of the Board
Trevor John Lockett – Executive Director
Louis James Panaccio – Non-Executive Director
David John White – Non-Executive Director
Eduardo Vom – Non-Executive Director

confirmed that the antibodies are stable, and the test is reproducible, which significantly de-risks Rhythm's technology.

Adjunct Biomarker Development – Nearing Completion

The several adjunct biomarkers are expected to support the key lead biomarker, as part of Rhythm's proprietary algorithm Test Kit.

ColoSTAT®'s anticipated adjunct biomarkers have been optimised and are currently undergoing technical-validation. Rhythm anticipates the final data analysis and individual reports to be completed within Q1FY'21.

Rhythm's ColoSTAT® will predominantly use its own version of antibodies which are intended to be combined in the one final Test Kit. This will enable 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.

ISO Certification – Another Step towards Commercialisation

Rhythm successfully maintained its certification to the International Standard for In-Vitro Diagnostics and Medical Devices (ISO 13485:2016). The audit was conducted by the British Standards Institution (BSI). This certification is an important step in achieving European market entry via a CE Mark and for the Australian market, via the Therapeutic Goods Administration (TGA).

COVID-19 Update – No Material Change to Previous Update

As per the Company's COVID 19 Update (released 9 April 2020), Rhythm is pleased to have been able to maintain its Research & Development staff within the laboratory. The Company has experienced some delays in the receipt of various materials from international suppliers primarily due to the backlog and re-routing of ports associated with freight processing, particularly in Victoria.

As previously indicated, delays continue to be experienced within patient recruitment and some blood sample collection for both Study 6 and the clinical trial (Study 7).

Within patient recruitment for Study 7, existing Melbourne sites are not currently recruiting due to internal resourcing shortages as a result of concentration on COVID 19. This delay could be further exacerbated by the Victorian State Government's announcement on 28 July 2020, that there will be a suspension of elective surgery other than for Category 1 and the 'most urgent' Category 2 patients. Routine colonoscopy procedures typically fall under Category 2. This has been decided as a result of increased COVID-19 cases, to effect an increase in human health resource capacity and in order to release beds within the hospitals.

As a result, Rhythm is working closely with its Clinical Research Organisation (CRO) and is actively seeking to broaden the locations for clinical trial sites nationally, with the 3 largest hospitals currently appointed to the clinical trial, being based in Melbourne, Victoria.

With the impact of Covid-19 affecting the development program and Rhythm's partner suppliers, the Company is unable at this time to provide a specific, updated timeframe for the achievement of its key milestones, associated with the clinical trial, CE Mark and TGA regulatory submissions. Rhythm will continue to assess the development schedule and provide updates of key deliverables accordingly.

Clinical Trial – Recruitment Challenges remain / Progressing Additional Sites

Clinical Trial recruitment remains paused, with most currently approved hospital sites being based in Victoria. As highlighted above, Rhythm is reviewing potential clinical trial sites on a national level, both in metropolitan and regional locations. Despite the current conditions, including hospitals re-deploying

clinical trial staff to other departments, Rhythm is progressing discussions and feasibility assessments, albeit at a slower pace than previously typical for new sites to be appointed to the trial.

Rhythm anticipate having commenced appointing new, alternative sites in 1QFY21 (subject to the individual hospitals internal governance and approval processes).

Regulatory – Reviewing EU & TGA Pathway

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 be included in the application to the Therapeutic Goods Administration (TGA) for approval in Australia and support ColoSTAT®'s marketing upon application for CE mark in the European Union (EU).

The Company is currently reviewing the EU regulatory process, with consideration being given towards applying for a CE Mark in advance of the completion of the final clinical trial (Study 7) report. This will be guided by appropriate, satisfactory, and robust data available from Study 6 and our ongoing verification program. Noting that an earlier CE application will not likely lead to immediate sales (or reimbursement), as key opinion leaders, physicians, surgeons, and governments will require significant robust clinical evidence, supported by Study 7, before recommending or endorsing ColoSTAT®.

Operations / Corporate – Broadening Board Experience

As per the 5 June 2020 release, Rhythm welcomed Mr Eduardo Vom to the Board. Eduardo is a Co-Founder and Executive Director of Planet Innovation, a technology development and commercialisation company. Planet Innovation is a 3-time winner of The Australian Financial Review's most Innovative Companies. He has a long association with RHY, being a shareholder and through his involvement as an advisor during the Company's inception.

As per the 10 June 2020 release, Rhythm changed its registered office address to Level 2, 480 Collins street, Melbourne 3000. Rhythm's Research, Development and Operational activities remain at the Bio21 Molecular Science & Biotechnology Institute in Parkville, Victoria.

Rhythm's R&D focus continues to be upon the completion of the technical validation of its own version of antibodies which is intended to be combined within the final ColoSTAT® test. Further to this, is the progress towards completing Study 6 testing activities. Successful progression of internal testing relating to Study 6 is expected to further de-risk the technology. In addition, it is an important input component to further train and enhance Rhythm's proprietary algorithm.

The global unmet need and market opportunity for Rhythm's ColoSTAT® test kit has not diminished despite the current global conditions. The Company remains confident on executing upon its development plan.

Related Party Payments

In line with its obligations under ASX Listing Rule 5.3.5, Rhythm Biosciences Limited notes that the only payments to related parties of the Company, as advised in the Appendix 4C for the period ended 30 June 2020, pertain to payments to directors for fees, salary and superannuation.

Rhythm finished the June 2020 quarter with a cash balance of \$1.8 million.

Capital Raise

On 23 July 2020, Rhythm announced it will conduct a Placement and Non-Renounceable Rights Issue ("Offer") to raise approximately \$6.0 million.

In recognition of the strong support shown from Rhythm's longstanding shareholders, the Board elected to favour its existing loyal shareholder base in this discounted capital raising, by deciding not to utilise

a broker, despite offers. Hence, the majority of funds is expected to be raised from existing shareholders, predominantly via a widespread Rights Issue. The price set of \$0.06 per share represents a discount of 23% to the lowest traded price of \$0.078, during the price setting period. Key details are as follows:

Placement

Placement to issue 40,112,500 new fully paid ordinary shares at an issue price of \$0.06 (6 cents) on the following basis:

- 15,112,500 shares pursuant to Listing Rule 7.1 (15% Placement capacity) to sophisticated, professional and other exempt investors, representing circa \$0.9 million; and
- 25,000,000 shares to Rhythm Non-Executive Chairman, Mr Otto Buttula (and/or nominees), representing a \$1.5 million commitment, subject to shareholder approval.

The Placement will raise approximately \$2.4 million before costs. A commitment fee of 5% of the respective amounts subscribed will be paid to each of the subscribers under the Placement.

Rights Offer on a 3 for 5 Basis

The Non-Renounceable Rights Issue Offer is made to Eligible Shareholders to subscribe for three (3) new shares for every five (5) shares held, at an Offer price of \$0.06 (6 cents) per share to raise up to \$3.6 million before costs.

The Company has received firm commitments from third parties for up to the maximum amount sought of \$2.25 million of any shortfall available under the Rights Issue. A commitment fee of 5% of the respective amounts subscribed will be paid to each of the above Shortfall Subscribers.

Directors retain the right for up to 3 months after the close of the Offer to place the balance of any New Shares not taken up by Eligible Shareholders and the Shortfall Subscribers.

As per the 23 July 2020 release, indicative timetable as below:

Indicative Capital Raising Timetable¹ Event	Date
Capital Raising announcement and company resumes trading	Thursday, 23 July 2020
Record Date	Tuesday, 28 July 2020
Allotment of New Shares under Placement (other than Related Party Placement)	Wednesday, 29 July 2020
Dispatch of Offer Booklet and Rights Issue Offer opens	Friday, 31 July 2020
General Meeting held	Tuesday, 25 August 2020
Allotment of New Shares under Related Party Placement (assuming shareholder approval obtained)	Thursday, 27 August 2020
Closing of Rights Issue Offer	5.00pm Friday, 28 August 2020
Allotment and issue of New Shares under Rights Issue Offer	Thursday, 3 September 2020
Expected normal trading of New Shares under Rights Issue Offer	Friday, 4 September 2020

1. Dates / times are indicative and subject to change. All times / dates are in reference to Australian Eastern Standard Time

With the authority of the Board.

For further information, please contact:

Glenn Gilbert
Chief Executive Officer
+61 3 8256 2880

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

59 619 459 335

Quarter ended ("current quarter")

30 JUNE 2020

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	(828)	(2,541)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(120)	(507)
(f) administration and corporate costs	(97)	(538)
1.3 Dividends received (see note 3)		
1.4 Interest received	9	47
1.5 Interest and other costs of finance paid	(2)	(8)
1.6 Income taxes paid		
1.7 Government grants and tax incentives		744
1.8 Other (COVID-19 Government stimulus)	50	63
1.9 Net cash from / (used in) operating activities	(988)	(2,740)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(24)	(45)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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	(24)	(45)

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)	(145)
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)	(145)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,850	4,728
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(988)	(2,740)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(24)	(45)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(40)	(145)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	1,798	1,798

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	298	835
5.2	Call deposits	1,500	2,015
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)	1,798	2,850

6. Payments to related parties of the entity and their associates

6.1 Aggregate amount of payments to related parties and their associates included in item 1

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

**Current quarter
\$A'000**

57

-

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 consulting services.

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	8	8
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 Total financing facilities	8	8

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)	(988)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	1,798
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	1,798
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	1.82

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

- 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: Yes

- 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: The Company will rely on its existing cash resources and future capital raising (either debt and/or equity), including its ability to place securities under LR7.1 and LR7.1A to fund its current activities. In addition, the Company refers to its announcement dated 23 July 2020 regarding a capital raising to raise approximately \$6 million via a placement and non renounceable rights issue.


- Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: In light of the above factors, the Company believes that it will have sufficient cash to fund its existing activities. The Company's Board and Management is focused on meeting its current objectives and confirm that it is in compliance with ASX Listing Rules, in particular, Listing Rule 3.1.

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:29 July 2020.....

Authorised by: 
Glenn Gilbert – Chief Executive Officer
(With authority 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.