

## Rhythm Biosciences Quarterly Report - June 2021

**30 July 2021, Melbourne:** For the quarter ended 30 June 2021, transformative medical diagnostics company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**), continued to deliver meaningful progress towards the commercialisation of its intended first product, ColoSTAT<sup>®</sup>, a simple blood test for the detection of colorectal cancer, aimed at global mass market screening.

### Core Technology

- Proprietary algorithm underpinning the ColoSTAT<sup>®</sup> technology continues to be enhanced;
- Rhythm confirmed a promising new enhancement that has the potential to further increase the accuracy of ColoSTAT<sup>®</sup>, with the inclusion of known Lifestyle Risk Factors (LRF), as part of the Company's cancer detection technology. LRF include diet, weight, exercise, smoking and type 2 diabetes, all of which have been strongly linked to the incidence risk of colorectal cancer;
- Rhythm included only one of these easily obtainable LRF datapoints, which improved the accuracy (Sensitivity) of the ColoSTAT<sup>®</sup> test from 84% to 88%.

**Table 1 - ColoSTAT<sup>®</sup> Performance Comparison -Study 6 vs LRF Enhancement**

	Specificity <sup>2</sup>	Sensitivity <sup>1</sup>
<b>ColoSTAT<sup>®</sup> - Study 6 (16 March 2021)</b>	95%	84%
<b>ColoSTAT<sup>®</sup> - Study 6 + LRF Enhancement (5 May 2021)</b>	<b>95%</b>	<b>88%</b>

- Further testing is being conducted to determine the commercial availability of the LRF enhancement in the final ColoSTAT<sup>®</sup> test.

### Commercialisation – Accelerated Strategy

Following the exceptional performance results exhibited by ColoSTAT<sup>®</sup> in Study 6 and the LRF algorithm enhancement work, the Company confirmed an accelerated commercialisation strategy, focusing on “path to market activities”, which include:

#### USA Market Entry

- Incorporate a 100% owned USA domiciled entity;
- Appoint appropriate Board, inclusive of USA based Directors;
- Target approved Clinical Laboratory Improvement Amendments (CLIA) laboratory via a lab developed test (LDT), appropriate for ColoSTAT<sup>®</sup>; and
- Commence initial stages of FDA approval pathway, ultimately leading to FDA clearance or approval.

#### Platform Technology Expansion

- Confirm initial data that Rhythm's key lead biomarker has global application and is highly expressed in a range of cancers;

- Set up separate corporate entities in Australia to exploit these new platform technologies and newly developed IP, targeting other cancers;
- Expands upon our simple, low cost, mass market cancer diagnostics strategy; and
- Aim to be capital-light, using existing, validated biomarker tests and exploring opportunities for collaboration and non-dilutive grants.

### ***Regulatory entry for Europe (CE Mark) and Australia (TGA)***

- Confirmed approach to submit for CE Mark approval in advance of Study 7 completion and TGA (Australia) regulatory filing;
- CE Mark filing expected to be late 2021;
- CE mark filing contingent on confirmatory testing that is currently underway on batches of test kits received subsequent to the end of the current reporting period;
- Exploring opportunity for LDT in other countries as an initial beachhead entry; and
- Ongoing engagement with TGA regarding regulatory filing in Australia.

### ***Business Development & Intellectual Property***

- Initiate business development activities relating to the most beneficial and appropriate market entry strategies into Europe, Australia, New Zealand, China and broader Asian countries; and
- Patent granted in Brazil further strengthens Rhythm's global IP footprint.

### **Clinical Trial – Study 7**

- Recruitment for Study 7 continues to accelerate with final expected numbers required to be confirmed. Scope to reduce the initially expected 1,000 patients (being confirmed with the TGA);
- Confirmation on recruitment completion and expected submission dates to be provided in future market updates;
- All patients recruited in the trial continue to provide a faecal test, a colonoscopy and a blood draw-to be tested at the end of the recruitment period, with the most updated and appropriate ColoSTAT® test-kit and algorithm;
- The Company further progressed recruitment, confirming further clinical trial sites were operational. Two new sites joined the trial network, with patients being recruited across both;
  - CliniTrials, a network of clinicians with centralised administration was appointed. CliniTrials brings over 20 years of experience and represents six sites in Western Australia, which include large patient populations across Perth, Mandurah and the Busselton region; and
  - Sonic Clinical Services' Independent Practitioner Network (IPN) Medical Centres, a division of Sonic Healthcare (ASX: SHL) also joined the ColoSTAT® Clinical Trial. IPN Medical Centres boast Australia's largest network of medical centres, with more than 2,000 doctors across 160 medical centres nationally. IPN provides more than 10 million patient consultations every year.

### **COVID-19 Update – As per last quarter**

- No Material Change to the Previous Update. The Company continues to actively manage against any delays and impacts to the international supply chains and sourcing of raw materials as it relates to production and supply.
- Rhythm continues to work with its suppliers to reduce any COVID-19 impact.

## Related Party Payments

- In line with its obligations under ASX Listing Rule 5.3.5, Rhythm notes that the only payments to related parties of the Company, as advised in the Appendix 4C for the period ended 30 June 2021, pertain to payments to directors for fees, salary and superannuation.

## Corporate

- Cash at bank at the end of the Quarter was \$2.23m
- 

## Subsequent to period end

### Capital Raise ~\$4.3m via Rights Offer and Top-Up Facility to Shareholders

- On 30 July 2021, Rhythm announced it would conduct a Non-Renounceable Rights Issue (“Offer”) to raise approximately \$4.3 million before costs. The Offer is expected to close on 3 September 2021.

In recognition of the strong support shown by Rhythm’s longstanding shareholders, the Board elected to favour its existing loyal shareholder base in this discounted capital raising and options issue, by deciding not to utilise a broker or accept institutional monies, despite these offers being made.

- The Offer to existing shareholders will comprise a 1 for 40 Rights Issue at \$0.85 per share, with attaching options. Shareholders taking up their Rights will be awarded unlisted Options, comprising 1 Class A Option and 1 Class B Option for every two Rights taken up.
  - Class A Options will have an exercise price of \$1.20 and expire on 31 August 2022; and
  - Class B Options will have an exercise price of \$1.80 and expire on 31 July 2024.

### Commitments Received for \$2.75m

- Rhythm has received firm commitments from third parties for up to the maximum amount sought of \$2.75 million of any shortfall available under the Rights Issue.
- The firm commitments were led by current shareholder and successful small cap investor John Hancock for \$0.95m and the Chairman, Otto Buttula, for \$0.25m.

**Mr Hancock commented:** *“I welcome the opportunity to increase my exposure to Rhythm via this Issue. In healthcare I look for products that are simple, effective and reduce costs with a large addressable market and the innovative ColoSTAT® product, developed from research by Rhythm and the CSIRO, has potential to be a global game changer in the early mass market screening for colorectal cancer.”*

### Board of Directors Restructure

- Mr David White resigned from the Rhythm Board to take a position on its United States (US) subsidiary Board, ensuring the maintenance of corporate knowledge and business know-how. Mr White is a resident of the US and has strong on the ground experience with parties with which Rhythm intends to engage.

### USA entity established

- On 15 July 2021, Rhythm announced that it had incorporated a US domiciled company, IchorDX, Inc., as its 100% owned US subsidiary. Initial Directors have been appointed, with Mr Otto Buttula as President, Mr Glenn Gilbert as Vice President and Secretary and Mr David White as Non-Executive Director.

## Human Resources –Employee LTIP

- The Board approved a LTIP for all Rhythm employees as part of the Company’s Employee Share Ownership Plan (ESOP). The plan comprised of long-term options to be allocated to Rhythm employees, aligning their interests with that of shareholders.

## Review of Prior (Q2FY’21) Stated Value Inflection Points

- ✓ Additional trial site recruitment – **ACHIEVED**
- ✓ Finalise European/Australian regulatory submission pathway – **COMMENCED & ON TRACK**
- ✓ Outline USA market entry strategy – **ACHIEVED**
- ✓ Commencement of platform technology opportunities – **ACHIEVED**

## Future Value Inflection Points

Matters we expect to deliver upon in the next two quarters include:

- Completion of Clinical Trial (Study 7) recruitment;
- Complete remaining testing requirements for CE Mark submission;
- File for CE Mark in late 2021;
- Consider and establish US entity advisors;
- Progress platform technology R&D plans; and
- Explore commercialisation pathways for ColoSTAT® in various jurisdictions.

**Released with the authority of the Board.**

For further information, please contact:

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Chief Executive Officer  
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## About Rhythm Biosciences

Rhythm Biosciences (ASX: RHY) is a transformative, predictive diagnostics company, specialising in early cancer detection. Rhythm's initial business pursuit is centred upon technology originally developed by the CSIRO and involves the development and commercialisation of 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<sup>®</sup>, 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<sup>®</sup> also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

ColoSTAT<sup>®</sup> is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT<sup>®</sup> has the potential to play an important role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Globally, over 850,000 people die from colorectal cancer each year. Colorectal cancer is typically diagnosed at a later stage when there is a poor prognosis for long-term survival. Annual estimated unscreened 50-74-year old's is estimated at +130m for the US, EU and AU alone, with this market potential being more than \$6.5b.

## 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 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(2,253)	(5,478)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(102)	(444)
(f) administration and corporate costs	(100)	(645)
1.3 Dividends received (see note 3)		
1.4 Interest received	2	21
1.5 Interest and other costs of finance paid		(2)
1.6 Income taxes paid		
1.7 Government grants and tax incentives		1,109
1.8 Other (COVID-19 Government stimulus)		50
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,453)</b>	<b>(5,389)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(4)	(65)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
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)		
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(4)</b>	<b>(65)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		6,034
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	120	135
3.4	Transaction costs related to issues of equity securities or convertible debt securities		(224)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		(61)
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>120</b>	<b>5,884</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	4,565	1,798
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,453)	(5,389)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(65)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	120	5,884
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>2,228</b>	<b>2,228</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	2,228	2,065
5.2	Call deposits		2,500
5.3	Bank overdrafts		
5.4	Other (provide details)		
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,228</b>	<b>4,565</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	79
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<p>Payments in 6.1 relate to Director fees and consulting services.</p> <p><i>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.</i></p>		



## Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>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.</i>		
7.1 Loan facilities		
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 <b>Total financing facilities</b>		
7.5 <b>Unused financing facilities available at quarter end</b>		
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.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,453)
8.2 Cash and cash equivalents at quarter end (item 4.6)	2,228
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	2,228
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	0.91
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 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: Yes	
8.6.2 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: As announced on 30 July 2021, the Company intends to undertake a non renounceable rights issue (rights issue) to raise up to \$4.3m before associated costs. In addition, the Company has received firm commitments for \$2.75m for shortfall under the proposed rights issue.	

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


Answer: 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

*Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.*

## 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 July 2021.....

Authorised by:   
Glenn Gilbert - CEO  
(with authority of 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.