ASX Announcement
ASX: RHY

Rhythm Biosciences Quarterly Report – December 2020

Highlights:

- ✓ **ColoSTAT® prototype test-kit completed, outperforming current market screening standard;**
- ✓ **US Patent granted for ColoSTAT® strengthens global footprint;**
- ✓ **Global manufacturer Biotem appointed, design transfer commenced;**
- ✓ **Total of nine clinical trial sites now operational;**
- ✓ **Receipt of $1.1 million Research and Development Tax Refund; and**
- ✓ **Well-funded with $6.02 million cash at bank as at 31 December 2020.**

Subsequent to period-end:

- ✓ **Initial prototype kits received from Biotem, early testing indicates performance on par with previous superior RHY results; and**
- ✓ **Two new sites, in Concord Repatriation Hospital and Bendigo Cancer Center appointed to Rhythm's clinical trial (Study 7).**

28 January 2021, Melbourne: For the quarter ended 31 December 2020, transformative medical diagnostics company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**), continued the excellent progress of its ColoSTAT® test-kit which is expected to be commercialised as a globally marketed, low-cost, simple blood test for the detection of colorectal cancer, aimed at mass-market screening.

Development update

The Rhythm development team has made excellent progress, hitting all milestones forecast for the quarter.

Research & Development - ColoSTAT® Prototype Complete, Outperforms FIT

Rhythm confirmed in November that the ColoSTAT® prototype test-kit had been successfully completed. Preliminary test results demonstrated superior performance to both:

a) the globally accepted current market standard faecal immunochemical test (FIT); and
b) previous testing data generated by the CSIRO, on commercially sourced individual biomarker test-kits.

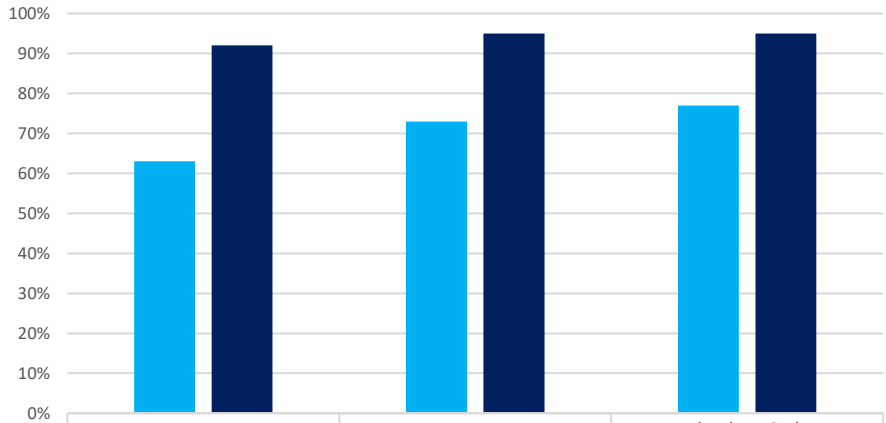
This milestone was significant as it underpins the global mass market commercial potential of ColoSTAT® as an effective screening test which is beneficial to patients, physicians, national healthcare systems, and governments.

ColoSTAT® prototype test

Rhythm completed a study using 200 blood samples (n=200) made up of 100 known cancerous and 100 known healthy samples. The preliminary results demonstrated that the ColoSTAT® prototype test-kit not only outperforms the previous reported faecal test results, but also outperforms previous studies conducted by both the CSIRO and earlier internal Rhythm test results.

The ColoSTAT® prototype test-kit encompasses five individual biomarker tests that have been technically validated. Results for each biomarker are fed into Rhythm's proprietary algorithm, which are then combined and processed with all relevant data to deliver a final performance result.

The study concluded that the ColoSTAT® prototype test-kit showed high accuracy for the detection of colorectal cancer, across all genders, and could accurately distinguish between cancerous and healthy blood samples at a specificity of 95%. A graphical and tabular summary of the results and comparison against the current market standard faecal immunochemical test (FIT) and prior CSIRO studies is shown below in Figure 1.



	FIT (80ug/g)	CSIRO	Rhythm Only (preliminary results)
Sensitivity (%)	63%	73%	77%
Specificity (%)	92%	95%	95%

Figure 1: Summary of ColoSTAT® prototype test-kit performance[1],[2] vs the current market standard faecal immunochemical test (FIT) and previous CSIRO test work

The faecal immunochemical test (FIT) is widely used as a colorectal cancer detection test in Australia and elsewhere globally. Unfortunately, the test only detects the presence of blood in the stool and experiences sub-optimal compliance in all countries, with only 40% of high-risk patients completing the test in Australia. One of the significant benefits of ColoSTAT® is that we expect to increase the compliance rate whilst having the potential to widen the patient pool outside of the standard 50 to 74-year-old

[1] Sensitivity is the ability of the test to correctly identify those patients with colorectal cancer, that is, the percentage of people with colorectal cancer who are correctly identified as having illness.

[2] Specificity is the ability of the test to correctly identify people who do not have colorectal cancer, that is, the percentage of people without colorectal cancer who are correctly identified as not having cancer.

bracket. This is particularly important as colorectal cancer is the most common cause of cancer deaths for those aged between 30-35 in Australia.

Intellectual Property - US Patent Granted for ColoSTAT®

The US patent covers defined core biomarkers that form part of ColoSTAT®. Further biomarkers are described in the claim and can be added to these core markers, providing optionality in the future, if required. The granting of the patent is a strong outcome for Rhythm given less than 35% of diagnostic patents applications are approved by the USPTO[3].

Global Market Opportunity

The US represents one of the largest diagnostic markets in the world. The addition of a US patent sees Rhythm expand its global footprint and ultimately, access to a global addressable screening market of close to 800 million people. In the US, the current 50-74 year old screening eligible population is ~94 million people. This market could grow in the short term by a further 21%, following the US Preventative Services Task Force recommendation that the colorectal cancer screening age be reduced, with screening beginning at 45 years. As a result, where the expansion in the screening age group occurs in other markets, it is expected that the current global addressable market will also increase considerably.

Table 1: Current Global Addressable Market (number of people)[4]

50–74-year-old population	US	EUROPE	CHINA	JAPAN	AUSTRALIA	TOTAL
	93.6M	231.2M	396.6M	41.5M	6.7M	**769.6M**

Rhythm's ColoSTAT® blood test will be a low-cost option, that is designed to ensure the Company can effectively access the significant mass screening opportunity in each market and transform the method colorectal cancer is detected globally. Importantly, the test is designed to integrate with existing pathology infrastructure and instrumentation and is therefore equipment agnostic.

Global Patent Position

Rhythm has now been granted patents for the diagnosis of colorectal cancer in 18 countries, which represent an addressable screening population of almost 800 million people:

- USA
- Australia
- China
- Japan
- United Kingdom
- Europe – Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxemburg, Netherlands, Norway, Spain, Sweden, and Switzerland

Rhythm is working towards filing further patents during 2021 that will continue to build upon the existing solid, global patent position.

[3] World Intellectual Property Indicators 2017
[4] Internal Company data

Manufacturing - Biotem Appointed

France based Biotem Limited, was appointed by Rhythm as the global manufacturer of its ColoSTAT® test-kit. Biotem were chosen following a robust due diligence process to select a manufacturer for the ColoSTAT® test-kit that could execute on Rhythm's ambition to address the global unmet need for the early detection of colorectal cancer. With over 40 years of immunoassay development and manufacturing experience, Biotem has the capability to deliver the optimization and process validation of the manufacturing procedure and the ability to economically produce large-scale quantities of the ColoSTAT® test-kit.

Design transfer of the core technology to Rhythm's global manufacturer, Biotem, has been successfully completed. The initial small-scale manufacturing of ColoSTAT® prototype test-kits by Biotem commenced in December 2020 (as announced on 2 December 2020) and were subsequently delivered to Rhythm ahead of schedule in late December.

Rhythm has commenced initial performance testing on the Biotem manufactured ColoSTAT® prototype test-kits on cancerous and healthy blood samples, which will form Study 6. Full testing of all samples is ongoing. Study 6 remains on track for completion by March 2021.

Early quality assurance and performance test work on the Biotem manufactured test-kits indicate comparable performance to the Rhythm prototype test-kit results (see ASX announcement 12 November 2020), which were found to be consistent and reproducible. The Company is highly encouraged by these early results.

Rhythm work to conclude remaining supply agreements to ensure ongoing supply capabilities of some raw materials to both Rhythm's laboratories and the Biotem manufacturing facility.

Clinical Trial – Additional Sites Signed and Recruiting / Reviewing Further Sites

During the quarter, the Company welcomed Northern Beaches Clinical Research (NBCR) to join Rhythm's Clinical Trial (Study 7). NBCR is based in Sydney's northern suburbs, and importantly has capability to access a number of private and public recruitment sites across northern Sydney. Subsequent to period end, Concord Repatriation Hospital and Bendigo Cancer Center were appointed to the trial.

A total of nine sites are now operational as part of Rhythm's Clinical Trial for ColoSTAT®. Recruitment progress varies from state to state, due to ongoing COVID procedures within the hospitals and specifically the appropriate resourcing of the trial sites clinical trials department. Rhythm continues to review the existing clinical trial sites to ensure that resourcing is / will be applied as it was at the time of signing and appointing the respective trials sites moving forward.

Site feasibility assessments are ongoing, with further sites anticipated to join in the coming months to accelerate recruitment. Rhythm have adopted a competitive recruitment remuneration strategy across all trial sites, whereby each site is remunerated (excluding non-material one off set up costs) for the number of patients they recruit to the trial.

Table 2: Clinical Trial Sites Appointed at 31 Dec 2020

Clinical Trial Site	Principal Investigator
Lyell McEwin Hospital *Adelaide, SA*	Professor Rajvinder Singh, Director of Gastroenterology
Monash Health *Melbourne, VIC*	Associate Professor, Dr Stephen Pianko Gastroenterologist and Head of Clinical Trials
The Alfred Hospital *Melbourne, VIC*	Associate Professor, Gregor Brown Head of Endoscopy
Royal Melbourne Hospital *Melbourne, VIC*	Professor Finlay Macrae Head, Colorectal Medicine and Genetics
John Hunter Hospital *Newcastle, NSW*	Doctor Alkesh Zala Gastroenterologist
Illawarra Health & Medical Research Institute *Wollongong, NSW*	Professor Philip Clingan OAM Medical Oncologist and Director
Northern Beaches Clinical Research *Sydney, NSW*	Dr Anthony McGirr Anesthetist
Concord Repatriation Hospital (Concord) *Sydney NSW*	Dr Emily He Gastroenterologist
Bendigo Cancer Center *Bendigo, VIC*	Dr Sam Harris Medical Oncologist

The Company was pleased to receive positive media coverage recently with a 9news report outlining the push to make the national bowel cancer screening program available to younger Australians, following a report showing an increasing number of deaths in people aged 45 to 49.

Click link to watch the report: www.9news/Rhythm

Figure 2: 9news Media coverage

COVID-19 Update – No Material Change to Previous Update

The Company continues to progress scientific and market activities to advance the development plan to commercialise ColoSTAT®. Pleasingly, COVID-19 related delays in receiving materials within Australia have begun to normalise. Internationally, raw material procurement, supply and transport from and within the USA and Europe continue to be impacted by COVID-19. Rhythm continues to monitor and work with suppliers to ensure delivery of materials in as timely manner as practicable. The Company notes that due to Rhythm's robust quality assurance program, we do not expect any delay to impact the quality or performance of the test-kits.

Similarly, delays continue to be experienced within patient recruitment for the clinical trial (Study 7), specifically the Victorian and SA trial sites. Rhythm is critically reviewing the existing trial sites to ascertain their capability to recruit appropriately for Rhythm's requirements. With the impact of COVID-19 affecting the 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 accordingly. Nevertheless, Study 6, remains on track to complete in Q3FY'21.

Annual General Meeting

A General Meeting of shareholders was held via a virtual meeting on 18 November 2020, with all resolutions passed by the requisite majority on a show of hands.

Resolutions related to the issue of the:

- Non-binding resolution to adopt the Remuneration Report;
- Re-election of Mr Louis Panaccio as a director;
- Election of Mr Otto Buttula as a director;
- Election of Mr Eduardo Vom as a director;
- Approval of the 10% placement facility;
- Appointment of auditor – BDO Audit Pty Ltd;
- Approval to issue options – to Trevor Lockett;
- Adoption of the employee incentive scheme;
- Amendment of the constitution; and
- Renewal of the proportional takeover provisions in the constitution.

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 31 December 2020, pertain to payments to directors for fees, salary and superannuation.

Corporate

Cash at bank at the end of the Quarter was $6.02m.

Review of Prior (Q1FY'21) Stated Value Inflection Points

- ✓ Preliminary specificity and sensitivity results - **ACHIEVED**
- ✓ Additional trial site recruitment - **ACHIEVED**
- ✓ Prototype test-kit completion - **ACHIEVED**
- ✓ Transfer of prototype test-kit to high volume manufacturer - **ACHIEVED**
- ✓ Study 6 completion - **ON TRACK**

Future Value Inflection Points

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

- ➢ Study 6 completion;
- ➢ Confirmation of Sensitivity and Specificity results in a third-party test kit environment;
- ➢ Additional trial site recruitment;
- ➢ Receipt of further test kits for quality and verification testing;
- ➢ Finalising remaining supply agreements;

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

For further information, please contact:

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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®, 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 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	**Quarter ended ("current quarter")**
59 619 459 335	31 DECEMBER 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(877)	(2,053)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs (not included above)	(110)	(241)
	(f) administration and corporate costs	(270)	(400)
1.3	Dividends received (see note 3)		
1.4	Interest received	9	17
1.5	Interest and other costs of finance paid		(2)
1.6	Income taxes paid		
1.7	Government grants and tax incentives	1,109	1,109
1.8	Other (COVID-19 Government stimulus)	12	50
1.9	**Net cash from / (used in) operating activities**	**(127)**	**(1,520)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(8)	(20)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**(8)**	**(20)**

3.	**Cash flows from financing activities**		
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		
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	(16)	(50)
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**	**(16)**	**5,760**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,169	1,798
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(127)	(1,520)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(8)	(20)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(16)	5,760
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**6,018**	**6,018**

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	1,518	1,669
5.2	Call deposits	4,500	4,500
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)**	**6,018**	**6,169**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	86
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Payments in 6.1 relate to Director fees and consulting services.

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.

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	11	11
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**	11	11

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.

The loan facility relates to a rent lease liability recorded under Accounting Standard AASB 16.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(127)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,018
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,018
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	47.4

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.

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: N/A

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: N/A

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: N/A

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: ...28 January 2021.....

Authorised by: .....
Glenn Gilbert – CEO

(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.