

Rhythm Biosciences Quarterly Report – December 2022

Transformative cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) is pleased to provide an update on activities, for the 3-month period ending 31 December 2022, with respect to progress for the commercialisation of ColoSTAT®, its simple blood test for the detection of colorectal cancer, aimed at global mass market screening.

Commercialisation

▪ **Regulatory**

✓ **Australia - Therapeutic Goods Administration (TGA) Approval for ColoSTAT® for sale in the Australian market:**

- ✓ The Company filed its complete submission with the TGA for the listing of ColoSTAT® on the Australian Register of Therapeutic Goods (ARTG). The TGA has acknowledged it is assessing the filing, with no further formal correspondence being received;
- ✓ The Company acknowledges that the review process has taken longer than initially envisaged when filed but notes that, due to Covid-19 and a backlog in medical device assessments, the median review period of the TGA has lengthened, particularly in regard to new medical devices; and
- ✓ The Company and its advisors remain confident in the validity of its filing and will update the market accordingly as further substantive progress is made.

✓ **New Zealand - Medsafe and listing on Web Assisted Notification of Devices (WAND) database:**

- ✓ Rhythm completed the process to achieve authorisation as a manufacturer of ColoSTAT® with Medsafe, the Medicines and Medical Devices Safety Authority in New Zealand; and
- ✓ The regulatory milestone means that the Company can now market ColoSTAT® for sale in New Zealand, progress pre-sales activities and advance partnership discussions.

▪ **Partnering / commercialisation deals (Domestic and International)**

Rhythm is intentionally being selective as to who we partner with to appoint distributors/partners on commercially favourable terms that will deliver solid medium to long term growth and profitability.

- ✓ **AUSTRALIA** – The Company remains in ongoing discussions with multiple potential major partners, and also in direct communication with State and Federal government officials.
- ✓ **NEW ZEALAND** – The Company is currently in discussions with potential partners.
- ✓ **ASIAN REGION** – Rhythm is in ongoing dialogue with several companies across the Asian region. Particular partners have regional capacity, whilst some more tailored and country specific priorities. Pricing and manufacturing capacity is particularly important in this region, with Rhythm paying close attention to the companies that have strong payer and Government relationships.

- ✓ **EUROPE** – Rhythm is in dialogue with a variety of companies, of differing sizes in various countries within Europe, all of which have differentiated risk appetites. Discussions remain ongoing and are at various levels of advancement. Similar to Asia, some potential partners would prefer regional style deals, whereas others may be country specific. Rhythm is in the fortunate position of having a unique test, that has a significant unmet need and strong demand.
- ✓ **U.S.A.** – The Company held discussions with several major potential CLIA laboratory partners and intends to expedite market entry during the course of CY'23 via the Lab Developed Test (LDT) pathway in the first instance.
- **Manufacturing scale up**
 - ✓ Rhythm assessed market feedback regarding expected demand in various countries leading to a focus on additional manufacturing capability required in additional geographies;
 - ✓ A U.S.A. based manufacturing company was engaged during the quarter to support market entry with respect to the U.S.A. It is foreseen that this manufacturer will also have capacity to support Rhythm's existing third-party manufacturer, France based Biotem, in global supply;
 - ✓ Associated feasibility and scale up of commercial manufacturing works are advancing ahead of planned production runs of commercial ColoSTAT® test-kits in 2H'FY'23; and
 - ✓ The Company intends to examine the feasibility of manufacturing domestically.
- **ColoSTAT® marketing program**

Rhythm progressed several initiatives related to product marketing, partnerships, and potential customer engagement activities, which included:

 - ✓ In final stages of the launch of a new Company website to appeal to a broader customer market and provide a more informative and engaging experience;
 - ✓ Engaged market participants and associations to assist in raising broader awareness of ColoSTAT® for initial customer markets;
 - ✓ Planning for education programs with GP, government, insurance, health and medical associations; and
 - ✓ The Company commissioned a global third party, Clarivate, to conduct health economic/cost benefit modelling to further support marketing efforts and the next stages of commercialisation, including reimbursement. The output will generate an interactive model that highlights the specific benefits of ColoSTAT® which can be tailored for Government, Private Health Insurers and other payors alike.

Core Technology

- **Final Study Report**
 - ✓ Rhythm is advancing the identification of the most applicable journals for publication of the Study 7 clinical trial results.
- **Platform Expansion Program with Other Cancers**
 - ✓ The Company continues to pursue its technology platform expansion program leveraging the key lead biomarker for its initial bowel cancer screening product, ColoSTAT®.

- ✓ Leading biomarkers have been identified that are critical to progress research and development into each other target cancers: Breast, Lung, Cervical, Pancreatic and Gastric;
- ✓ Second additional cancer target commenced with Rhythm appointing the Baker Institute, as second bioanalytical partner, to advance the development program for platform expansion into additional cancers; and
- ✓ Adding to the recent engagement of Agilex Biolabs, the appointments cover two of Rhythm's largest cancer market opportunities identified, outside of near-term entry into colorectal cancer screening.

COVID-19 Update

- No material changes to previous updates. The Company continues to actively manage the ongoing delays and significant impacts to international supply chains and the sourcing of raw materials, as it relates to our production and supply and is working with its suppliers to reduce its effect where practicable.

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 2022, pertain to payments to directors for fees, salary and superannuation.

Corporate

- Cash at bank at the end of the Quarter was \$8.9M.
- Executive management team was expanded with two key appointments:
 - Ms. Elena Deak, Chief Commercial Officer; and
 - Mr. Paul Smith, Chief Financial Officer / Joint Company Secretary.
- Non-executive Director, Mr. Eduardo Vom retired from the Board, effective 29 November 2022.
- The Company's Annual General Meeting was held on Tuesday, 29 November 2022 with all resolutions carried; and
- Rhythm received a Research and Development (R&D) tax refund of \$2.7M.

Subsequent to period end:

- Ms Sue MacLeman appointed to the RHY Board, bringing a skillset that will be highly valuable for the Company as it progresses its commercialisation of ColoSTAT®.

Review of Prior (Q2FY'23) Stated Value Inflection Points

- TGA approval for ColoSTAT® for sale in the Australian market – **COMMENCED & ONGOING**
- Regulatory approvals in additional countries – **COMMENCED & ONGOING**
- Commercialisation / partnering agreements with third parties – **COMMENCED & ONGOING**
- Progress our technology expansion program – **COMMENCED & ONGOING**

Future Value Inflection Points

Matters we expect to deliver upon in the 2H'FY'23 include:

- Additional manufacturer approved on the Rhythm's Quality Management System (QMS);
- TGA approval for ColoSTAT® for sale in the Australian market;
- Commercialisation / partnering agreements with third parties; and
- Advancement of our technology platform expansion program.

- ENDS -

Authorised for release by the Board.

For further information contact:

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About Rhythm Biosciences

Rhythm Biosciences is focused on becoming a globally significant, transformative, predictive diagnostics company, specialising in cancer detection technology. The Company is currently developing ColoSTAT® - a simple, low-cost, blood test for global mass market detection of colorectal cancer.

Worldwide, colorectal cancer is the third most common cancer in men and the second most common in women, accounting for an estimated 1.9 million new cases and 935,000 deaths annually.

In an effort to reduce the global burden, many countries have implemented screening programs aimed at early detection. These programs are predominantly administered with a faecal immunochemical test (FIT) for the assessment of colorectal cancer risk, with a positive result referred for a colonoscopy. FIT only analyses the presence of blood in faeces, which can occur for several reasons other than cancer, therefore it is not designed as an accurate test for cancer. Many people simply don't take the test for fear of an unnecessary colonoscopy procedure, unpleasantness, difficulty, or for religious/cultural reasons. There is currently no appropriate blood test alternative.

Rhythm aims to transform the global mass-market for colorectal cancer detection with ColoSTAT® its simple, low-cost blood test that is fit for purpose, meaning that it is designed to actually detect colorectal cancer. Since listing on the ASX in 2017, the Company has run a successful multi-year research and development program that has delivered technical validation of the core biomarker technology, being reproducible and stable. The ColoSTAT® test-kit was manufactured in 2021 and delivered performance testing that outperforms the current market standard faecal immunochemical test utilising Rhythm's proprietary algorithm. The Company is progressing regulatory, manufacturing and scale up activities ahead of market entry in FY23.

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 a key role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Rhythm's initial targeted global addressable population is over 800 million people which are over 50 years of age. Almost 70%, or 550 million people, are not currently screened for colorectal cancer due to the limitations of the current faecal based testing regime. This "at risk" population is also expanding with the disease growing rapidly in much younger age groups. Early detection and intervention can lead to cure in over 90 per cent of new cases, therefore the need for effective screening and early intervention has the potential to save a significant number of lives. Rhythm estimates today's colorectal cancer screening market alone to be worth in excess of \$38 billion.

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")

31 DECEMBER 2022

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	(1,833)	(3,515)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(193)	(384)
(f) administration and corporate costs	(453)	(723)
1.3 Dividends received (see note 3)		
1.4 Interest received	66	104
1.5 Interest and other costs of finance paid	(2)	(4)
1.6 Income taxes paid		
1.7 Government grants and tax incentives	2,706	2,721
1.8 Other		
1.9 Net cash from / (used in) operating activities	291	(1,801)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(40)	(55)
(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	(40)	(55)

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	125	3,216
3.4	Transaction costs related to issues of equity securities or convertible debt securities		(18)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(21)	(42)
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	104	3,156

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,495	7,550
4.2	Net cash from / (used in) operating activities (item 1.9 above)	291	(1,801)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(40)	(55)

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)	104	3,156
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	8,850	8,850

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	3,850	8,495
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other – short term deposit	5,000	
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	8,850	8,495

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	240
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 salaries.</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>		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	Total financing facilities		
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.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	291
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,850
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,850
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
<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: 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		
<i>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.</i>		

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.

31 JAN 2023

Date:



Authorised by:
(Name of body or officer authorising release – see note 4)

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.