# ASX Announcement

31 October 2023



## **Rhythm Biosciences Quarterly Report – September 2023**

## **Highlights**

- UK entry plans advance, with the establishment of a local subsidiary and an Advisory Board meeting;
- ColoSTAT® Automation project is underway and on-track;
- Platform expansion outcomes in Breast Cancer positive; and
- Significant R&D Tax Incentive submitted and expected to be received in CY'23. •

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: RHY) (Rhythm or the **Company**) is pleased to provide an update on its activities for the quarterly period ended 30 September 2023.

#### Commercialisation

#### Establishment of UK Subsidiary

As announced on 3 July 2023, to assist with the Company's launch into the UK marketplace, Rhythm Biosciences UK Limited, a 100% wholly owned subsidiary was established. This will assist in the importation and distribution channels of ColoSTAT<sup>®</sup> into the UK and other parts of Europe.

#### Advisory Board with UK Key Opinion Leaders

In September an Advisory Board meeting was held with Link Medical and 11 influential UK based medical specialists to discuss and advise on how to position and utilise ColoSTAT® in the UK.

One of the key objectives of this group was to invite centres across England to participate in the validation of ColoSTAT<sup>®</sup>. Following on from the work of the Advisory Board, validation centres are being identified to utilise ColoSTAT® and to generate post-market data. This project is expected to commence early in the 2024 calendar year.

#### Automation Project Commenced through partnership with Nutripath

As announced on 13 September 2023, Rhythm executed an Automation Agreement with Melbournebased, medical laboratory, Nutripath Pty Ltd a specialty clinical laboratory, that supports healthcare providers in health and wellbeing pathology testing.

Collaborating with Nutripath and one of its diagnostic machine vendors, Tecan Australia Pty Ltd (a subsidiary of Swiss based Tecan Group Ltd), the parties are streamlining the previously manual process of ColoSTAT<sup>®</sup> to the automated Tecan EVO machine.

Nutripath has a broad reach across the Asia Pacific region, with business channels extending across New Zealand, the Pacific Islands and South East Asia. In addition, it owns a CLIA certified laboratory in the USA.

**Rhythm Biosciences Ltd** ACN 619 459 335 ASX: RHY

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Trevor Lockett Rachel David Louis Panaccio

**Executive Chairman** Independent, Deputy Chair **Executive Director** Non-Executive Director Non-Executive Director

www.rhythmbio.com



#### **Core Technology**

#### • Platform Expansion Breast Cancer

As announced on 21 September 2023, the Company together with Agilex Biolabs (a Healius Ltd subsidiary ASX: HLS) identified 4 biomarkers that exhibit a strong correlation with specific breast cancer subtypes.

These encouraging results warrant confirmation in a larger sample set and justify the continuation and advancement of the project.

Verification of these results would support the case for investment in a new R&D program to develop, validate, clinically evaluate the performance of the biomarkers, and translate these results into a commercially scalable, proprietary blood test for the early detection of breast cancer.

#### Corporate

- On 4 July 2023, the Board appointed Ms Sue MacLeman to the new position of Independent Deputy Chair.
- On 25 July 2023, the Company presented at the 2023 Bioshares Summit in Hobart, Tasmania.
- Rhythm received further TGA Freedom of Information (FOI) requests relating to the ColoSTAT<sup>®</sup> TGA application. The Company completed and filed its response in conjunction with the TGA.
- On 31 August 2023, the Company released its 2023 Annual Report.
- Cash at bank at the end of the quarter was ~\$1.5m.
- The Company with its professional advisers has submitted an R&D Tax Incentive claim totalling ~\$3.5m, with the expectation that this will be received in the current quarter.

#### Subsequent to Period-End

- On 10 October 2023, the Company held its 2023 Annual General Meeting, with all resolutions put forward being passed.
- On 12 October 2023, FIL Investment Management (Hong Kong) Limited notified the ASX that it had become a Substantial Shareholder at 5.02%.

#### **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 September 2023, pertain to payments to directors for fees, salary, and superannuation.

#### Review of Prior (1QFY'24) Stated Value Inflection Points

- Automation Project ONGOING
- Research & Development Tax Incentive SUBMITTED
- Financial Year End Reporting and AGM COMPLETED
- Commercialisation / partnering agreements with third parties ONGOING
- Progression of the Company's technology platform expansion program INITIAL OUTCOMES RELEASED ON BREAST CANCER SCREENING & ONGOING



#### **Future Value Inflection Points**

Matters we expect to deliver upon in 2QFY'24 include:

- New patent application lodgement to extend the duration for ColoSTAT<sup>®</sup> protection in a broader set of jurisdictions.
- Submit ColoSTAT<sup>®</sup> publication.
- Establishment of ColoSTAT <sup>®</sup> Medical Advisory Committee.
- Release of resubmission plan for ColoSTAT<sup>®</sup>, incorporating IVDR standards both within Australia and the EU.
- Further progress with validation centre project rollout in the UK.
- Finalise Automation Project with Nutripath.

#### **Positive Developments in CRC Screening**

• NHMRC endorses lowering the bowel cancer screening start age, expanding ColoSTAT®'s potential market

A key five-year Bowel Cancer Australia campaign has reached a milestone with updated clinical practice guidelines lowering the bowel cancer screening start age recently endorsed by the National Health and Medical Research Council (NHMRC).

For the first time, population screening (for people at average risk of developing bowel cancer, i.e., without any symptoms) is recommended every two years for people aged 45-74 (previously 50-74), along with a lowering of the National Bowel Cancer Screening Program (NBCSP) start age from 50 to 45.

People aged 40-44 (previously 45-49) are also able to request screening via their healthcare professional prior to receiving their first NBCSP invitation. 1,716 Australians are diagnosed with bowel cancer under the age of 50 each year. People aged 40-49 account for 56 percent of new cases and 64 percent of deaths in those diagnosed under 50.

#### Bowel Cancer New Zealand

Years of advocacy for the screening age to be lowered by Bowel Cancer New Zealand has resulted in a commitment from both major political parties to bring bowel screening from 45 years old.

#### Frequently Asked Questions (FAQ)

The Company will be publishing an FAQ section on its website to better communicate with shareholder questions, whilst maintaining its 'best-practice' obligations under ASX disclosure policies. This new section will be available by the end of November 2023 at <u>www.rhythmbio.com</u>.

#### - ENDS -

Authorised for release by the Board.

For further information contact:

Mr Otto Buttula Executive Chairman Ms Elena Deak Chief Commercial Officer

# RHYTHM BIOSCIENCES

#### **About Rhythm Biosciences**

Rhythm Biosciences Ltd (ASX: RHY) is an Australian innovative, medical diagnostics company aimed at delivering simple, affordable blood tests for accurate and early detection of cancers. Rhythm is focused on improving patient outcomes through detection at the earliest possible stage, reducing the global burden of cancer and saving lives.

Rhythm Biosciences is committed to working with likeminded global partners to achieve commercialisation and distribution of these simple solutions.

The company was founded in 2017 and is headquartered in Melbourne, Australia. For more information, visit rhythmbio.com and follow the company on LinkedIn and Twitter.

#### About ColoSTAT®

Colorectal cancer (CRC), also referred to as bowel cancer, is the second leading cause of cancer deaths globally. If diagnosed early, colorectal cancer is curable.

The ColoSTAT<sup>®</sup> Test-Kit is Rhythm Bioscience's simple blood test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood presence of CRC. The test can be used as an alternative for individuals who are unable or unwilling to participate in current screening programs.

The ColoSTAT<sup>®</sup> Test-Kit is based on research from Australia's CSIRO and is patent protected internationally. It has the potential to play a key role in reducing the mortality rate and healthcare costs associated with colorectal cancer.

# 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 SEPTEMBER 2023

Con	solidated 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	(1,165)	(1,165)
	(b) product manufacturing and operating costs	(1,168)	(1,168)
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs (not included above)	(114)	(114)
	(f) administration and corporate costs	(327)	(327)
1.3	Dividends received (see note 3)		
1.4	Interest received	27	27
1.5	Interest and other costs of finance paid	(1)	(1)
1.6	Income taxes paid		
1.7	Government grants and tax incentives		
1.8	Other		
1.9	Net cash from / (used in) operating activities	(2,748)	(2,748)

2.	Ca	sh flows from investing activities		
2.1	l Pay	ments to acquire or for:		
	(a)	entities		
	(b)	businesses		
	(c)	property, plant and equipment	(79)	(79)
	(d)	investments		
	(e)	intellectual property		
	(f)	other non-current assets		

ASX Listing Rules Appendix 4C (17/07/20) + See chapter 19 of the ASX Listing Rules for defined terms.

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 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	(79)	(79

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	270	270
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(23)	(23)
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	247	247

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,124	4,124
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,748)	(2,748)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(79)	(79)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	247	247
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	1,544	1,544

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	1,544	4,124
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other – short term deposit		
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,544	4,124

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	132
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
Paym	ents in 6.1 relate to Director fees and salaries.	
	f any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ ation for, such payments.	e a description of, and an

vailable at quarter end	
it is secured or unsecured. If a or are proposed to be entered	ny additional financing
	vailable at quarter end cription of each facility above, in r it is secured or unsecured. If a o or are proposed to be entered s 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)	(2,748)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,544
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,544
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.56

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: Reducing. Following a period of raw material and inventory build-up, monthly net operating cash outflows are expected to reflect a noticeable reduction over future months. That said, the Company has in place an extensive R&D and validation program that it believes represents an appropriate use of shareholder funds.

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: No. The Company is anticipating a significant R&D refund well in excess of its FY'22 receipt (FY'22: \$2.7m). This is expected to be received before the end of CY'23. In the absence of receipt of the R&D refund in a timely manner the Company has recourse to a range of service providers who can pre-pay R&D refunds. The Company believes it has sufficient working capital to meet its obligations and proposed business plans for the near term.

A	
Answer	Yes. The Company expects to be able to continue its operations and meet business objectives as required under the Corporations Act. As noted above, t
	Company expects a substantial R&D refund in the current calendar year. T
	Company is also reviewing its activities to identify where current inventories can
	converted into cash inflows in addition to additional cost savings in order to exte
	its cash reserves.

#### **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: .....31 OCTOBER 2023.....

Authorised by: .....BY THE BOARD..... (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.