

Melissa Kostopoulos  
Listing Compliance - Melbourne  
ASX Compliance Pty Ltd  
525 Collins Street  
North Tower Level 4  
MELBOURNE VIC 3000

Dear Melissa

## Rhythm Biosciences Limited (RHY) – ASX Query Letter

We refer to your letter of 16 October 2023 and provide the following responses to your questions:

1. ***Noting that RHY appears to have been in possession of a request from the TGA to provide further information on 8 June 2022, and RHY appears to have provided the TGA with risk assessment documentation on 6 July 2022, please explain why RHY deemed it appropriate to state on 15 December 2022 that no further formal correspondence had been received.***

RHY updated the ASX market on the ASX MAP before the opening of trading on 12 May 2022 that it had lodged its TGA application for the listing of ColoSTAT® on the Australian Register of Therapeutic Goods (**RHY's ARTG Listing application**) and that "...the TGA will assess Rhythm's ARTG Listing [application] along with key technical documents...".

Any such TGA application is subject to mandatory "audit" as part of that TGA review and registration process for such a medical device (in accordance with the TGA's published guidelines, see link below):

<https://www.tga.gov.au/resources/resource/guidance/auditing-medical-device-including-ivd-medical-device-applications>

As part of the customary TGA audit process for such applications, there are typically a number of audit-like process interactions with the assigned TGA team over the review period and the provision to the TGA of additional documentation or information in response. In respect of RHY's ARTG Listing application, the Company engaged an independent third-party consultancy firm to assist in preparing RHY's ARTG Listing application and responding to the TGA during this audit process.

As mentioned, this audit interaction is typical of ARTG applications for such medical devices and in the ASX letter of 16 October 2023 you have referred to two of those audit interactions (namely TGA's request of 8 June 2022 and 6 July 2022), whereas there were a number of such interactions. The Company viewed such standard audit interactions as "*business as usual*" and therefore not material for disclosure to the ASX market under the Company's continuous disclosure obligations and not constituting the formal communication from the TGA of any decision on RHY's ARTG Listing application.

It is important to note that the TGA audit requests of 8 June 2022 and 6 July 2022 were part of this standard TGA audit process / review – and did **not** contain any assessment of the merits of RHY's ARTG Listing application. It reflects the typical interaction with the TGA regarding such applications that any applicant customarily experiences and RHY note this is consistent with disclosures / approach taken by other ASX listed life sciences companies.

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

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### Directors

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Sue MacLeman  
Trevor Lockett  
Rachel David  
Louis Panaccio

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

Accordingly, as RHY had not received any indication from the TGA of an assessment or opinion on the merits of the RHY's ARTG Listing application, in the RHY ASX Announcement on 15 December 2022 RHY did state, after disclosing the TGA had acknowledged receipt of the RHY's ARTG Listing application that the TGA "...is assessing the filing with no further formal [TGA] correspondence being received".

**2. Does RHY consider any of the information disclosed in the [2023] AGM Presentation to be material information which required disclosure pursuant to Listing Rule 3.1?**

Yes. RHY, out of an abundance of caution, was of the view generally that the written presentation to shareholders at the 2023 Annual General Meeting was of itself material for disclosure. The 2023 AGM Presentation included a general update on the Company's activities and, as a whole, provided material information.

While marked as "price sensitive" under ASX Listing Rule 3.1, RHY also notes that ASX Listing Rule 3.13.3 also provides that such prepared documents to be delivered at a meeting must be provided to the ASX MAP prior to the start of the meeting.

In particular the reference in the 2023 AGM Presentation to the matters referred to in paragraph D of your Query Letter were material, but each item was itself already known or capable of being calculated / determined by the market in that:

- the change in regulatory standards [*new in vitro diagnostic medical devices regulation standards (IVDR) which will replace the current in vitro diagnostic medical devices directive (IVDD) on May 2026 for Class C devices in the EU*] was actually already public information.
- RHY's cash position as at 30 September 2023 could also be calculated based on the Company's Appendix 4C cash position as at 30 June 2023 [of \$4.127 million] and estimated cash burn lodged with the ASX MAP on 31 July 2023.

**3. If the answer to question 2 is "yes":**

**3.1 Please identify that information; when RHY became aware of that information; and whether the disclosure of that information via the AGM Presentation was consistent with RHY's obligation to disclose that information 'immediately'.**

As outlined above, it was the AGM Presentation itself as a whole which RHY viewed as material given it collated information into one document – whereas that information was otherwise only available from (a) collating prior ASX MAP announcements by RHY; or (b) available on government website site [in the TGA publications of the new standards].

As soon as the AGM Presentation was finalised and approved by the RHY Board – it was "immediately" released to the market, approximately 45 minutes before the actual 2023 AGM meeting.

**3.2 Please explain whether RHY considers the AGM Presentation was compliant with section 13 of Guidance Note 14 (reproduced at Paragraph F above).**

Yes, as mentioned it was the 2023 AGM Presentation as a whole collating information available in other RHY ASX announcements plus publicly available information on the TGA website – that RHY viewed as price sensitive, not any individual item of information in that 2023 AGM Presentation.

In the light of the restriction on the number of words / letters that can be included in the "header" for an ASX announcement – RHY believed the header "*RHY 2023 AGM Presentation*" was sufficient to identify the nature of the document and draw to the market's attention that this document would provide a general update on the Company's activities over the last 12 months and future business activities.

**4. If the answer to question 2 is "no":**

Not applicable.

**5. Please confirm that RHY is complying with the Listing Rules and, in particular, Listing Rule 3.1.**

Yes.

**6. Please confirm that RHY's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of RHY with delegated authority from the board to respond to ASX on disclosure matters.**

Yes.

**- ENDS -**

**Authorisation & Additional Information**

**This announcement was authorised by the Board of Directors of Rhythm Biosciences Limited.**

**For further information contact us via [investor@rhythmbio.com](mailto:investor@rhythmbio.com) or on +61 3 8256 2880:**

<b>Mr Otto Buttula</b> Executive Chairman	<b>Ms Andrea Steele</b> Joint Company Secretary
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**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](http://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® 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® 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.

16 October 2023

Reference: 82083

Ms Andrea Steele  
General Counsel  
Rhythm Biosciences Limited  
Bio21 Institute, 30 Flemington Road  
Parkville, Vic 3010

By email: andrea.steele@rhythmbio.com

Dear Ms Steele

### Rhythm Biosciences Limited ('RHY'): Query Letter

ASX refers to the following:

- A. A letter from the Therapeutic Goods Administration of Australia ('TGA') to RHY titled 'Notice under section 41JA of the Therapeutic Goods Act 1989 Requiring information/documents to be provided' (the '**TGA Letter**'). This letter was produced under a Freedom of Information query and became available on 10 October 2023. A copy of the TGA Letter is available here:

[https://www.righttoknow.org.au/request/10701/response/32283/attach/9/Document%201%20AR.pdf?cookie\\_passthrough=1](https://www.righttoknow.org.au/request/10701/response/32283/attach/9/Document%201%20AR.pdf?cookie_passthrough=1)

The TGA Letter stated (relevantly, emphasis added):

- i. *"On 8 June 2022 you were requested to provide detailed information regarding the:*
- Risk management report including protocol, report, risk-matrix table, FMEA and risk benefit statement; and*
  - Post-Market Data inclusive of all recalls, adverse events, CAPAs, customer complaints and regulatory refusals."*
- ii. *"You have provided Revision 06 of the preliminary risk assessment documentation, signed 6 July 2022".*
- B. RHY's announcement titled 'Market Update' lodged on the ASX Market Announcements Platform ('MAP') on 15 December 2022, which stated (relevantly, emphasis added):
- "On 12 May 2022, 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.*
- The Company remains confident in the validity of its filing and will update the market accordingly as further substantive progress is made."*
- C. RHY's announcement titled 'RHY 2023 AGM Presentation', lodged on MAP on 10 October 2023 (the '**AGM Presentation**'). ASX notes that RHY indicated the AGM Presentation was 'market sensitive' when it was submitted to MAP.

- D. RHY's response dated 13 October 2023 to ASX's price query dated 12 October 2023, which stated in response to question 2 concerning whether RHY was aware of any other explanation for the decrease in the price of its securities:

*"The Company held its 2023 Annual General Meeting (AGM) on 10 October 2023 commencing at 11.00am and prior to that meeting the Company released to the ASX Market Announcements Platform its 2023 AGM Investor Presentation which contained:*

- an outline of the new in vitro diagnostic medical devices regulation standards (IVDR) which will replace the current in vitro diagnostic medical devices directive (IVDD) on May 2026 for Class C devices in the EU (initially outlined in the Appendix 4C on 31 July 2023);*
- reference to the revised TGA guidance released in a June 2023 document which signaled its intention to adopt similarly stringent criteria consistent with these increased requirements for moving from the IVDD CE to an IVDR CE standard (initially outlined in the Appendix 4C on 31 July 2023);*
- RHY's intention to submit its application to ensure compliance with the new standards (which will entail additional work) (initially outlined in the Appendix 4C on 31 July 2023);*
- confirmation that our current regulatory approvals remain valid;*
- disclosure of RHY's cash balance of \$1.6 million on 30 September 2023; and*
- RHY's forecast material R&D tax refund which is expected in the short term (as discussed)."*

- E. Listing Rule 3.1, which requires a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.

- F. Section 13 of Guidance Note 14, which states (relevantly):

*"ASX has experienced difficulties in the past with announcements that have been given a fairly innocuous header (such as "Chairman's Address to AGM") but have had market sensitive material embedded in them. ASX would ask listed entities to ensure that the header to such an announcement clearly identifies the fact that it contains market sensitive information (eg "Chairman's Address to AGM and Buyback Announcement") or, better still, that market sensitive announcements are made on a stand-alone basis and not embedded in other announcements that may not be market sensitive."*

### **Request for information**

Having regard to the above, ASX asks RHY to respond separately to each of the following questions and requests for information:

1. Noting that RHY appears to have been in possession of a request from the TGA to provide further information on 8 June 2022, and RHY appears to have provided the TGA with risk assessment documentation on 6 July 2022, please explain why RHY deemed it appropriate to state on 15 December 2022 that no further formal correspondence had been received.
2. Does RHY consider any of the information disclosed in the AGM Presentation to be material information which required disclosure pursuant to Listing Rule 3.1?
3. If the answer to question 2 is "yes":
  - 3.1 Please identify that information; when RHY became aware of that information; and whether the disclosure of that information via the AGM Presentation was consistent with RHY's obligation to disclose that information 'immediately'.

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- 3.2 Please explain whether RHY considers the AGM Presentation was compliant with section 13 of Guidance Note 14 (reproduced at Paragraph F above).
  4. If the answer to question 2 is “no”:
    - 4.1 Please explain why RHY indicated as such in its price query response.
    - 4.2 Please explain why RHY lodged the AGM Presentation as ‘market sensitive’ on MAP.
  5. Please confirm that RHY is complying with the Listing Rules and, in particular, Listing Rule 3.1.
  6. Please confirm that RHY’s responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of RHY with delegated authority from the board to respond to ASX on disclosure matters.

#### **When and where to send your response**

This request is made under Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **9:30 AM AEDT Thursday, 19 October 2023**. You should note that if the information requested by this letter is information required to be given to ASX under Listing Rule 3.1 and it does not fall within the exceptions mentioned in Listing Rule 3.1A, RHY’s obligation is to disclose the information ‘immediately’. This may require the information to be disclosed before the deadline set out in the previous paragraph and may require RHY to request a trading halt immediately.

Your response should be sent to me by e-mail at [ListingsComplianceMelbourne@asx.com.au](mailto:ListingsComplianceMelbourne@asx.com.au). It should not be sent directly to the ASX Market Announcements Office. This is to allow me to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

#### **Trading halt**

If you are unable to respond to this letter by the time specified above, you should discuss with us whether it is appropriate to request a trading halt in RHY’s securities under Listing Rule 17.1. If you wish a trading halt, you must tell us:

- the reasons for the trading halt;
- how long you want the trading halt to last;
- the event you expect to happen that will end the trading halt;
- that you are not aware of any reason why the trading halt should not be granted; and
- any other information necessary to inform the market about the trading halt, or that we ask for.

We require the request for a trading halt to be in writing. The trading halt cannot extend past the commencement of normal trading on the second day after the day on which it is granted. You can find further information about trading halts in Guidance Note 16 *Trading Halts & Voluntary Suspensions*.

#### **Suspension**

If you are unable to respond to this letter by the time specified above, ASX will likely suspend trading in RHY’s securities under Listing Rule 17.3.

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### **Listing Rules 3.1 and 3.1A**

In responding to this letter, you should have regard to RHY's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure*: Listing Rules 3.1 – 3.1B. It should be noted that RHY's obligation to disclose information under Listing Rule 3.1 is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

### **Release of correspondence between ASX and entity**

ASX reserves the right to release all or any part of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A.

### **Questions**

If you have any questions in relation to the above, please do not hesitate to contact me.

Yours sincerely

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**Melissa Kostopoulos**  
Senior Adviser, Listings Compliance