

## Response to ASX Query

Melissa Kostopoulos  
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Listings Compliance  
525 Collins Street,  
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By email: [ListingsComplianceMelbourne@asx.com.au](mailto:ListingsComplianceMelbourne@asx.com.au)

Dear Melissa,

Pursuant to our email exchange on Friday 19 May 2023, please find below the correspondence and answers to your respective questions to your query:

### **Rhythm Biosciences Limited ('RHY'): Query letter**

ASX refers to the following:

- A. RHY's announcement titled "UKCA Mark Granted for ColoSTAT" (the 'Announcement') released on the ASX Market Announcements Platform ('MAP') on 17 May 2023, disclosing that RHY's product, ColoSTAT, had been granted UK Conformity Assessment ('UKCA') ('Information').

ASX notes the Announcement was marked as 'market sensitive' by RHY when it was submitted to MAP.

- B. RHY's announcement titled "Change of Director's Interest Notice" released on MAP on 15 May 2023 (the 'Notice'), which disclosed the purchase of 683,895 RHY shares by entities related to RHY's Executive Chairman, Mr. Otto Buttula, on 12 May 2023 (the 'Trade').
- C. RHY's Securities Trading Policy, available on its website<sup>1</sup>, which states (relevantly):

*"All trading in securities by Restricted Persons must be in accordance with this Policy. Despite anything else in this Policy, Restricted Persons should not deal in the Company's securities when they possess Price Sensitive Information relating to the Company that is not generally available to the market..."*

*For all periods during which dealing in the Company's securities is permitted in accordance with this policy, Restricted Persons must obtain prior written approval to trade in securities..."*

*Any approval to deal in the Company's securities by a Restricted Person in accordance with this policy is automatically deemed to be withdrawn if the Restricted Person becomes aware of any price sensitive information prior to or during any approved dealing in the Company's securities."*

D. 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.

E. The definition of "aware" in Chapter 19 of the Listing Rules, which states that:

*"an entity becomes aware of information if, and as soon as, an officer of the entity (or, in the case of a trust, an officer of the responsible entity) has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity" and section 4.4 in Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B "When does an entity become aware of information."*

F. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure, provided that each of the following are satisfied.

"3.1A Listing rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:

3.1A.1 One or more of the following applies:

- It would be a breach of a law to disclose the information;
- The information concerns an incomplete proposal or negotiation;
- The information comprises matters of supposition or is insufficiently definite to warrant disclosure;
- The information is generated for the internal management purposes of the entity; or
- The information is a trade secret; and

3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and

3.1A.3 A reasonable person would not expect the information to be disclosed."

G. ASX's policy position on the concept of "confidentiality", which is detailed in section 5.8 of Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B. In particular, the Guidance Note states that:

*"Whether information has the quality of being confidential is a question of fact, not one of the intention or desire of the listed entity. Accordingly, even though an entity may consider information to be confidential and its disclosure to be a breach of confidence, if it is in fact disclosed by those who know it, then it ceases to be confidential information for the purposes of this rule."*

### **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. Does RHY consider the Information to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

### **RHY RESPONSE**

No. However, upon reflection the Information would likely not be seen as market sensitive – for the reasons below. Hence, a reasonable person would not consider the Information to be likely to have a material effect on the price or value of RHY securities.

The UKCA Mark Certification is largely equivalent to the CE Mark Certification achieved and announced to the ASX on 30 November 2021 and the Expansion Announcement for the UK as announced to the ASX on 6 January 2022.

Both these announcements had previously confirmed that ColoSTAT® could be marketed and sold within Great Britain.

The announcement made on 17 May 2023, reiterated that ColoSTAT® “fully conforms with the regulatory requirements for IVD products under the European Directives for IVD Medical Devices (98/79/EC).” This same sentence was released in the 6 January 2022 ASX announcement, however RHY added “...and the UKCA requirements”.

UKCA requirements are not mandatory, but were pursued for good order following BREXIT, as the UK still recognises the CE Mark. The decision to pursue and announce such was largely for marketing purposes. As stated in the quote “continues to validate”, clarifies that it is not a new validation.

The previous announcement expanding the CE Mark registration released to the ASX on 6 January 2022 had no material or sustained effect on the price or value of RHY securities.

This has been evidenced by the recent trading in RHY securities which have seen high volatility, but no sustained appreciation in the price or value of RHY securities.

Hence, it was deemed that the information was largely in the marketplace prior to the announcement of 17 May 2023, and it was a “localisation” to an already expanded UK/CE certification which had been released.

Therefore, it was deemed that the announcement would not have a material or sustainable effect on the price or value of RHY securities, as estimated by a reasonable person.

RHY also remains a “pre-revenue” Company and registration of its product in the UK remains a pre-requisite to commercialisation.

2. When did RHY become aware of the Information? In your answer, please confirm when the relevant “officer of the entity” came “into possession of the information in the course of the performance of their duties as an officer of that entity” as set out in paragraph E above.

#### **RHY RESPONSE**

On 9 May 2023, the UK notice of registration was received by the Head of Regulatory Affairs (working from home) who then forwarded this to the Chief Operating Officer (COO). No one else at RHY was aware of this notice. The COO then emailed it to the Chief Financial Officer (CFO) on the evening of 9 May 2023 (after market close). The (CFO) then emailed NWR (RHY’s external PR and media firm) a copy of the notice and requested a draft ASX announcement be prepared. At this time the Chief Executive Officer (CEO) and the Board of Directors were not informed of this notice as this was considered BAU (business as usual), consistent with prior updates to the ASX market and not considered to be market or price sensitive.

On 16 May 2023, the COO and Head of Regulatory Affairs confirmed receipt of confirmation of completion of UKCA registration process within a management meeting. The CFO confirmed such to the Executive Chairman in the early afternoon of the 16 May 2023 and a final ASX release was concluded for Board Approval.

3. If the answer to Question 1 is “no”: 3.1 please advise the basis for that view. 3.2 please explain why RHY lodged the announcement as ‘market sensitive’.

**RHY RESPONSE**

The answer to Question 1 is “no” and the reason it was incorrectly ticked as ‘market sensitive.’ This is habitually done by those persons lodging RHY’s ASX announcements, with all announcements marked as “market sensitive.” The basis for the answer is contained under Question 1.

In completing the electronic form for lodgment of ASX announcements – the prompts include the lodgment person to “tick the box” if market sensitive. As alluded to this had become the custom. The RHY Board has not made any consideration whether the “Information” was market sensitive and has not provided any direction to the RHY person authorised to lodge the ASX announcement that it was market sensitive.

This also seems to be the approach of most pre-revenue, ASX listed life science companies – which habitually mark all their announcements as ‘market sensitive’.

4. If the answer to Question 1 is “yes” and RHY first became aware of the Information before the Announcement was released on 17 May 2023, did RHY make any announcement prior to the relevant date which disclosed the information? If so, please provide details. If not, please explain why this Information was not released to the market at an earlier time, commenting specifically on when you believe RHY was obliged to release the Information under Listing Rules 3.1 and 3.1A and what steps RHY took to ensure that the Information was released promptly and without delay.

**RHY RESPONSE**

The answer to Question 1 is “no”.

5. Did Mr. Buttula seek approval or otherwise notify RHY of the intention to conduct the Trade, as required by RHY’s Securities Trading Policy? If so, when was the approval sought, and when was it granted?

**RHY RESPONSE**

On 6 March 2023, Mr. Buttula sought approval to purchase up to \$250,000 of RHY Shares, via email correspondence from the full Board of RHY Directors.

This request followed the reinstatement to quotation of RHY securities, post the announcement of the “Update to TGA Submission.”

This also had followed a “black out” trading period, given RHY’s Half-Yearly Report and review of TGA questions.

The “Update to TGA Submission”, was considered effectively a “cleansing” to the ASX market.

The full Board approved the ability for Mr. Buttula to purchase up to \$250,000 of RHY Shares.

A further “black out” ensued two weeks before the release of RHY’s 4C announcement on 27 April 2023.

On the morning of 9 May 2023, Mr. Buttula asked the CFO and Joint Company Secretary if there was anything outside the “ordinary course of business”, not already disclosed to the ASX market, which would preclude his ability to embark on the previously approved purchase of RHY securities. The CFO and Joint Company Secretary confirmed that there was nothing outside the “ordinary course of business” not disclosed to the ASX market which would preclude Mr. Buttula’s intended purchase of RHY securities.

Mr. Buttula's decision to begin purchasing RHY securities on 9 May 2023, followed a 31% fall in the share price since 28 April 2023.

In fact, on 9 May 2023, this share price level represented a new 2 ½ year low for RHY securities (last 11 November 2020 @ \$0.28). Before and at around this time Mr. Buttula received several comments from shareholders about whether he would be buying RHY shares to show support and belief in the Company.

The new lows being experienced in RHY's securities trading price was seemingly being caused by added selling pressure from a previous officer of the Company, being the recently departed CEO (as announced to the ASX on 19 April 2023) and RHY believes much of the selling volume during this period came from the selling by the departed CEO of RHY shares.

6. Was Mr. Buttula aware, in any capacity, of the Information before the Trade occurred?

**RHY RESPONSE**

No – in fact Mr. Buttula only became aware of the registration on 16 May 2023 17.42 AEST via email.

The reason Mr. Buttula did not buy after the 12 May 2023 was because the original order for \$250,000 in shares had been "completed" on 12 May 2023 (being the maximum authorised by the RHY Board in accordance with RHY Securities Trading Policy) and Mr. Buttula did not wish to trade leading into the week of the Board meeting on 17 May 2023.

The first time Mr. Buttula became aware of the registration (and as a result the Information) was on 16 May 2023 at 17.42 AEST via email. The final draft announcement was sent to the RHY Board on 16 May 2023 at 18.32 AEST, and then further in a draft set of Board papers which were circulated on 16 May 2023 at 17.56 AEST.

7. If the answer to question 6 is "yes":

- 7.1 Please explain how the Trade was compliant with the RHY's Securities Trading Policy.
- 7.2 Please outline any remedial action to be taken by RHY.

**RHY RESPONSE**

Not Applicable.

8. If the answer to question 6 is "no", is RHY of the view that its internal policies and procedures to identify material information and ensure its timely disclosure are sufficient?

**RHY RESPONSE**

As stated above the Information and the announcement of 17 May 2023 in hindsight were not market sensitive.

No assessment was made by the RHY Board or generally RHY that the "Information" was market sensitive. As mentioned, the RHY officer responsible for lodging the RHY announcement simply habitually checks the box (generated on an electronic lodgment) that the announcement was market sensitive.

In this regard:

- i) RHY is cognisant of the perceptions caused and has recently revisited its Securities Trading Policy (please see below in answer to question 10).

Further, the Company is in the process of instituting better and more immediate dissemination of

important information between its management and director levels.

A recognised failure has been that information may be privy to one party only (in this case the RHY Regulatory person) and this position is not full-time - hence there can be delays in its dissemination to the wider RHY management team and following this to the RHY directors. Please see response to question 9 Below for revised internal policies and procedures.

9. If the answer to question 8 is:
- 9.1 "yes", please explain the basis for that view, commenting specifically on the time taken from when RHY first became aware of the Information until its ultimate release on MAP; or
  - 9.2 "no", please outline any planned improvements to ensure material information is disclosed promptly and without delay.

#### **RHY RESPONSE**

RHY is articulating and in the process of enacting two major improvements to ensure information is disclosed promptly and without delay. These are being overseen by our contracted General Counsel and an Independent Director.

These include:

- i) A centralised email box to the CFO / Joint Company Secretary and COO for all Regulatory updates;
- ii) A process whereby information is immediately disseminated to the Executive Chairman (and when appointed the new RHY CEO) and where need be to the wider RHY Board; and
- iii) An assessment is made by the Executive Chairman (and where appointed RHY CEO) and if deemed "market sensitive" then an immediate imposition of a Company-wide "black out" for trading in RHY securities.

RHY then intends on achieving external review and verification from its external Legal Advisers on this process.

10. Does RHY consider its Securities Trading Policy to be sufficient to prevent the appearance of insider trading? If so, please provide the basis for that view. If not, please outline any planned improvements to RHY's Securities Trading Policy.

#### **RHY RESPONSE**

Yes, RHY considers its Securities Trading Policy to be sufficient to prevent the appearance of insider trading.

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

#### **RHY RESPONSE**

RHY confirms that it is fully compliant with all relevant Listing Rules and, in particular, Listing Rule 3.1.

12. 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.

#### **RHY RESPONSE**

RHY confirms that the responses to the questions furnished by ASX have been authorised and approved in accordance with its published continuous disclosure policy and by its Board of Directors.

Please contact me if you require any further information concerning this matter.

Yours sincerely



Mr. Paul Smith  
Chief Financial Officer and Company Secretary

- 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>Mr Paul Smith</b> CFO & Company Secretary
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19 May 2023

Reference: 74539

Mr Paul Smith  
Rhythm Biosciences Limited  
Company Secretary  
Bio21 Institute, 30 Flemington Road  
Parkville, Victoria 3010

By email: Paul.Smith@rhythmbio.com

Dear Mr Smith

### **Rhythm Biosciences Limited ('RHY'): Query letter**

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- E. The definition of "aware" in Chapter 19 of the Listing Rules, which states that:

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- F. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure, provided that each of the following are satisfied.

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<sup>1</sup> <https://rhythmbio.com/file/896/225?p=224>



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*“3.1A Listing rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:*

*3.1A.1 One or more of the following applies:*

- It would be a breach of a law to disclose the information;*
- The information concerns an incomplete proposal or negotiation;*
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- The information is generated for the internal management purposes of the entity; or*
- The information is a trade secret; and*

*3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and*

*3.1A.3 A reasonable person would not expect the information to be disclosed.”*

G. ASX’s policy position on the concept of “confidentiality”, which is detailed in section 5.8 of Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. In particular, the Guidance Note states that:

*“Whether information has the quality of being confidential is a question of fact, not one of the intention or desire of the listed entity. Accordingly, even though an entity may consider information to be confidential and its disclosure to be a breach of confidence, if it is in fact disclosed by those who know it, then it ceases to be confidential information for the purposes of this rule.”*

### **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. Does RHY consider the Information to be information that a reasonable person would expect to have a material effect on the price or value of its securities?
2. When did RHY become aware of the Information? In your answer, please confirm when the relevant “*officer of the entity*” came “*into possession of the information in the course of the performance of their duties as an officer of that entity*” as set out in paragraph E above.
3. If the answer to Question 1 is “no”:
  - 3.1 please advise the basis for that view.
  - 3.2 please explain why RHY lodged the announcement as ‘market sensitive’.
4. If the answer to Question 1 is “yes” and RHY first became aware of the Information before the Announcement was released on 17 May 2023, did RHY make any announcement prior to the relevant date which disclosed the information? If so, please provide details. If not, please explain why this Information was not released to the market at an earlier time, commenting specifically on when you believe RHY was obliged to release the Information under Listing Rules 3.1 and 3.1A and what steps RHY took to ensure that the Information was released promptly and without delay.
5. Did Mr Buttula seek approval or otherwise notify RHY of the intention to conduct the Trade, as required by RHY’s Securities Trading Policy? If so, when was the approval sought, and when was it granted?
6. Was Mr Buttula aware, in any capacity, of the Information before the Trade occurred?
7. If the answer to question 6 is “yes”:

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- 7.1 Please explain how the Trade was compliant with the RHY's Securities Trading Policy.
  - 7.2 Please outline any remedial action to be taken by RHY.
  8. If the answer to question 6 is "no", is RHY of the view that its internal policies and procedures to identify material information and ensure its timely disclosure are sufficient?
  9. If the answer to question 8 is:
    - 9.1 "yes", please explain the basis for that view, commenting specifically on the time taken from when RHY first became aware of the Information until its ultimate release on MAP; or
    - 9.2 "no", please outline any planned improvements to ensure material information is disclosed promptly and without delay.
  10. Does RHY consider its Securities Trading Policy to be sufficient to prevent the appearance of insider trading? If so, please provide the basis for that view. If not, please outline any planned improvements to RHY's Securities Trading Policy.
  11. Please confirm that RHY is complying with the Listing Rules and, in particular, Listing Rule 3.1.
  12. 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, 25 May 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*.

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## **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.

## **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**  
Adviser, Listings Compliance