

18 January 2021

BY EMAIL: ListingsComplianceMelbourne@asx.com.au

Ms Melissa Kostopoulos  
Corporate Adviser, ASX Listings Compliance (Melbourne)  
Rialto Towers  
525 Collins Street  
Melbourne Vic 3000

Dear Ms Kostopoulos

Aware query

I refer to your letter of 14 January 2021.

For ease of reference, terms used in this letter and not otherwise defined have the meaning given in your letter.

Our responses to your requests for information is set out below, using the numbering and headings in your letter.

**1. Does PNV 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?**

PNV sales performance is typically highly variable month on month due to the episodic nature of the indications its product is used for such as burns and trauma. Also, PNV is continually entering new markets where inherently sales are highly variable month on month. At the same time, as PNV enters new markets, it necessarily adds to its sales staff workforce to service those new markets, further diminishing the materiality of prior month sales results.

The sales results for Q1 and October and November 2020 were not released to the market due to the volatility of PNV's sales on a month-to-month basis and pending the outcome of sales results for December 2020 to complete the sales picture for the half-year. PNV did not consider these elements of this component to be material under the test in s677 of the Corporations Act.

ASX acknowledges<sup>1</sup> that the relevant test of when information is 'material', being the test in s677 of the Corporations Act, is an objective one and the subjective albeit honest opinion of PNV or its officers is not determinative. ASX also acknowledges that determining whether information is material can give rise to practical difficulties.

PNV has approached the question of disclosure of the Information on the assumption that the totality of the Information (not necessarily each individual component of the Information) is material for the purposes of s677.

**2. If the answer to question 1 is "no", please advise the basis for that view.**

Not applicable, in relation to the totality of the components making up 'Information'.

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<sup>1</sup> ASX Guidance Note 8 section 4.2, When is information market sensitive?.

### 3. When did PNV first become aware of the Information?

This is not necessarily a simple question to answer. Under the AASB Accounting Standards a 'sale' of a product can only be recognised once the product is in the customer's possession. This in turn requires obtaining proof of delivery from PNV's logistics partners globally for each sale to each customer.

PNV's customers are principally hospitals both in Australia and overseas that provide treatment for severe burns victims and trauma cases.

While PNV has experienced continuous rates of growth, actual sales depend on:

- (a) acceptance by a treating hospital of PNV's product as an efficacious burns and trauma treatment. Typically, this follows evaluations supervised by medical professionals at the hospital and approval by the hospitals VAC committee; and
- (b) random events such as house fires, bush fires, road, industrial and other accidents and in certain cases even volcanic eruptions generating patients requiring treatment in hospitals for severe burns and trauma that they have suffered.

Due to the episodic nature of burn and trauma cases and the various ways product can be provided to a hospital, either on consignment, from a sales representative or from our logistics partners, sales can have inherent constraints as to how and when they may be recognised. For example, product supplied to a hospital for the purpose of evaluation could not be recognised as a sale, even though the fact of the evaluation may give rise to a level of confidence on the part of PNV that sales to that hospital may subsequently arise.

PNV's approach to disclosure is consistent with ASX's own guidance<sup>2</sup> on compliance with the requirement for a listed entity to disclose material information 'promptly and without delay' after becoming aware of the information. Specifically, ASX notes that a period of time will 'necessarily pass' between when an entity first becomes obliged to give information to ASX under Listing Rule 3.1 and when it is able to give that information to ASX in the form of a market announcement. This passing of time, of itself, does not mean that there has been a 'delay' in the provision of the information to the ASX.

Reasons that ASX specifies may result in a listed entity taking longer to disclose information include:

- the forewarning (if any) the entity had of the information;
- the amount and complexity of the information concerned;
- the need in some cases to verify the accuracy or bona fides of the information;
- the need for an announcement to be carefully drawn so that it is accurate, complete and not misleading; and
- the need in some cases for an announcement to be approved by the entity's board or disclosure committee.

With that context, the following responses are provided with respect to each several component comprising, collectively with the other components, the 'Information':

(i) *H1 FY21 up 31% on H1 FY20*

This component of Information was not available until sales information for December 2020 had been finalised and verified in accordance with the AASB Accounting Standards. This occurred on Wednesday, 6 January 2021.

Before the component of Information was considered appropriate for disclosure, additional information was required to be sourced from PNV's management teams in each market in order to provide the necessary context and to avoid disclosure being misleading. Obtaining this additional information required among other things, liaising with PNV's distributors, and sales representatives located in overseas time zones, including the

<sup>2</sup> ASX Guidance Note 8 section 4.5, The meaning of "immediately"..

United States, necessarily resulting in delay in obtaining information suitable for disclosure. Feedback arising from this process was received on Saturday 9 January 2021, following which a number of drafts of the announcement were prepared over the balance of the weekend.

A draft of the announcement was then circulated to the PNV board for review and comment in the course of the day on Monday, 11 January 2021. Various comments were received and processed during course of the day leading to finalisation of the form of the announcement late in the evening. The announcement was then released to the market before 10.00am on Tuesday, 12 January 2021. A total of 8 confidential drafts of the announcement were prepared and circulated before the final version was finalised and released to the market.

*(ii) Strong sales Q1 FY21 up 75% on Q1 FY20*

PNV became aware of this component of Information on 2 October 2020 after sales for the month were verified.

*(iii) Slower than expected sales in October and November*

PNV became aware of sales for October 2020 and November 2020 on 4 November 2020 and 2 December 2020 respectively after sales for the relevant month had been verified consistently with the procedure described above.

Given that PNV sales performance is typically highly variable month on month for the reasons outlined above, PNV did not consider these elements of this component to be material in a s677 sense in the absence of information about PNV's sales performance for December 2020.

*(iv) United States*

*- Q1 FY 21 up 70% on Q1 FY20*

*- Q2 FY21 up 16% on Q2 FY20*

*- 1H FY21 up 41% on 1H FY20*

PNV became aware of the relevant sales information on 4 November and 2 December 2020 and 6 January 2021, as noted above.

PNV repeats its views about the materiality of this component of Information as for component (iii).

*(v) Barda*

*- YTD BARDA revenue lower than anticipated to the delay in obtaining our US FDA IDE approval. Recruitment of patients now scheduled for late Q3 FY21 and will be reflected in increased revenue*

PNV has released 3 announcements to ASX in relation to this component, ie:

- (a)** on 10 July 2020, delay in FDA approving the Pivotal Trial Protocol and delay in commencement of trial recruitment
- (b)** 11 September 2020, further feedback from the FDA on the Pivotal Trial Protocol and that it would take PolyNovo a number of weeks to attend to that feedback
- (c)** 13 November 2020, FDA approval of the Pivotal Trial IDE where PNV stated it would expect recruitment to occur early in CY21.

In its 12 January announcement, PNV stated that recruitment of patients is not 'scheduled for late Q3 FY21', which is the same timing as early CY21 disclosed in its 13 November announcement. PNV has updated the market on the trial delays and the market is aware that with any delay, BARDA revenue will be lower for the period.

ASX guidance<sup>3</sup> states that in assessing whether or not information is market sensitive and therefore needs to be disclosed under Listing Rule 3.1, the information needs to be looked at in context, rather than in isolation, against the backdrop of, among other things, any previous information that the entity has provided to the market including under its continuous or periodic disclosure obligations.

4. **If the answer to question 1 is "yes" and PNV first became aware of the Information before the relevant date, did PNV 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 PNV was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps PNV took to ensure that the information was released promptly and without delay.**

The only component of the Information that was subject to a PNV market release prior to 12 January 2021 was that relating to BARDA. As noted above, the BARDA component was subject to previous announcements on 10 July, 11 September and 13 November 2020.

As to those of the other components of the Information relating to circumstances that occurred prior to December 2020, these were not considered material in a s677 sense prior to receipt of verified December 2020 sales information. Specifically, the sales results for Q1 and October and November 2020 were not released to the market due to the volatility of PNV's sales on a month to month basis and pending the outcome of sales results for December 2020 to complete the sales picture for the half-year.

For example, despite sales for October and November, being less than expectations, sales for December in the US, NZ and Taiwan exceeded budget and all other markets performed well. As a fast growing business and consistently entering new markets, PNV expects sales results to continue to be volatile month to month until it gains significant market share in each of the markets in which it carries on business.

5. **In the reference to the Appendices 3Y referred to in paragraphs C, D and E, Trading Policy and Listing Rule 12.12 please confirm that the dealing disclosed in each Appendix 3Y complied with section 7 of the Trading Policy and if not, why not.**

Confirmed. The dealing disclosed in each such Appendix 3Y complied with section 7 of PNV's Trading Policy.

6. **In relation to the Trading Update, please provide clearer information as required by Guidance Note 8 highlighted at paragraph K as follows:**

- (a) **What the statement 'H1 FY21 up 31% on H1 FY20' is referring to (eg: revenue) and provide the H1 FY21 and H1 FY20 amounts.**

The statement refers to product sales.

H1 FY21 \$11.25 million / H1 FY 20 \$8.57 million.

- (b) **The Q1 FY21 and Q1 FY20 amounts in the statement 'Strong sales Q1 FY21 up 75% on Q1 FY20'.**

Q1 FY21 \$6.13 million / Q1 FY20 \$3.49 million.

- (c) **Further detail to the statement 'Slower than expected sales in October and November' including amounts.**

October 2020 sales were \$1.43 million and lower than budget.

November 2020 sales were \$1.40 million and lower than budget.

- (d) **What the statement 'Q1 FY21 up 70% on Q1 FY20' is referring to (eg: revenue) and provide the Q1 FY21 and Q1 FY20 amounts.**

<sup>3</sup> ASX Guidance Note 8, section 4.3, The need to assess information in context.

The statement refers to product sales.

Q1 FY21 \$USD 3.64 million / Q1 FY20 \$USD 2.14 million.

- (e) **What the statement 'Q2 FY21 up 16% on Q2 FY20' is referring to (eg: revenue) and also provide the Q2 FY21 and Q2 FY20 amounts.**

The statement refers to product sales.

Q2 FY21 \$USD 2.89 million / Q2 FY20 \$USD 2.48 million.

- (f) **What the statement '1H FY21 up 41% on 1H FY20' is referring to (eg: revenue) and also provide the 1H FY21 and 1H FY20 amounts.**

The statement refers to product sales.

1H FY21 \$USD 6.53 million / 1H FY20 \$USD 4.63 million.

- (g) **The revenue figures referred to in the statement 'YTD BARDA revenue lower than anticipated to the delay in obtaining our US FDA IDE approval. Recruitment of patients now scheduled for late Q3 FY21 and will be reflected in increased revenue'.**

H1 FY21 BARDA revenue \$1.35m

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

Confirmed. PNV is complying with the Listing Rules and, in particular, Listing Rule 3.1.

8. **Please confirm that PNV'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 PNV with delegated authority from the board to respond to ASX on disclosure matters.**

Confirmed.

Yours sincerely



**Jan Gielen**

CFO and Company Secretary



14 January 2021

Reference: ODIN29510

Mr Jan Gielen  
Company Secretary  
PolyNovo Limited  
2/320 Lorimer Street  
Port Melbourne Vic 3207

By email: jan.g@polynovo.com

Dear Mr Gielen

**PolyNovo Limited ('PNV'): General – Aware Query**

ASX Limited ('ASX') refers to the following:

A. PNV's announcement entitled 'Interim Trading Update' released on the ASX Market Announcements Platform ('MAP') on 12 January 2021 ('Trading Update'), which disclosed the following:

- (i) *'H1 FY21 up 31% on H1 FY20'*
- (ii) *'Strong sales Q1 FY21 up 75% on Q1 FY20'*
- (iii) *'Slower than expected sales in October and November.'*

...

- (iv) *'United States'*
  - *Q1 FY21 up 70% on Q1 FY20*
  - *Q2 FY21 up 16% on Q2 FY20*
  - *1H FY21 up 41% on 1H FY21'*

...

- (v) *'Barda'*
  - *YTD BARDA revenue lower than anticipated to the delay in obtaining our US FDA IDE approval. Recruitment of patients now scheduled for late Q3 FY21 and will be reflected in increased revenue.'*

(together, the 'Information').

B. PNV's securities trading policy which is available on the PNV company website at the following website address <https://polynovo.com/wp-content/uploads/2020/02/PolyNovo-Share-Trading-Policy.pdf> ('Trading Policy'), which states the following:

- '7. Clearance to deal'*
  - 7.1 A Specified Person must make a request in writing to the Company Secretary before dealing in Company Securities.*
  - 7.2 The Company Secretary must request clearance from the Approving Officers.*
  - 7.3 The Approving Officers must not give clearance if:*

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- (a) *there is a matter about which there is inside information in relation to Company Securities which the Specified Person is aware of when the Specified Person requests clearance or proposes to deal in Company Securities; or*
- (b) *the Approving Officers have any other reason to believe that the proposed dealing breaches this policy.*
- 7.4 *If clearance is given, the Specified Person must:*
- (a) *advise the Company Secretary of the dealing, including the number of securities bought or sold on specific dates; and*
- (b) *should material information become aware to the person then any unfilled order be cancelled.*
- 7.5 *The Company Secretary must keep a record of:*
- (a) *any information received from a Specified Person in connection with this policy;*
- (b) *any clearance given under this policy; and*
- (c) *the outcome of any cleared deal.'*
- C. PNV's Appendix 3Y lodged on MAP on 1 December 2021 for Mr Bruce Rathie, a Non-Executive Director of PNV, which discloses the sale of 355,555 ordinary shares at \$3.3594 per share on 1 December 2021 by Katrat Investments Pty Ltd, an entity related to Mr Bruce Rathie ('Rathie Appendix 3Y').
- D. PNV's Appendix 3Y lodged on MAP on 1 December 2021 for Mr Paul Brennan, Managing Director of PNV, which discloses the sale of 200,000 ordinary shares at \$3.39 per share on 1 December 2021 by Mr Paul Brennan ('Brennan Appendix 3Y').
- E. PNV's Appendix 3Y lodged on MAP on 2 December 2021 for Mr Leon Hoare, a Non-Executive Director of PNV, which discloses the sale of 100,000 ordinary shares at \$3.454 per share on 2 December 2021 by Mrs Helen Charles-Hoare, the spouse of Mr Leon Hoare ('Hoare Appendix 3Y').
- F. The change in the price of PNV's securities from a closing price of \$3.39 on Monday 11 January 2021 to a closing price of \$2.68 Wednesday 13 January 2021, subsequent to the release of the Information.
- G. 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.
- H. 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.'*
- I. 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.'*
- J. Listing Rule 12.12 which states:
- '12.12 At a minimum, an entity's trading policy must include the following information:*
- 12.12.1 The entity's closed periods.*
- 12.12.2 The restrictions on trading that apply to the entity's key management personnel.*
- 12.12.3 Any trading which is not subject to the entity's trading policy.*
- 12.12.4 Any exceptional circumstances in which the entity's key management personnel may be permitted to trade during a prohibited period with prior written clearance.*
- 12.12.5 The procedures for obtaining prior written clearance for trading under rule 12.12.4.'*
- K. Paragraph 10.4 of ASX Guidance Note 27- Trading Policies ('GN27') which states, among other things:
- 'If ASX has concerns that an entity may not be taking appropriate measures to enforce compliance with its trading policy, ASX may require the entity to give any information, document or explanation that ASX asks for to enable it to be satisfied that the entity is, and has been, complying with the Listing Rules. ASX can also impose a requirement with which the entity must comply in order to ensure compliance with the Listing Rules.'*
- GN27 references Listing Rule 18.7 which requires an entity to give ASX any information or explanation that ASX asks for to enable it to be satisfied that the entity is, and has been, complying with the Listing Rules.
- L. Guidance Note 8: *Continuous Disclosure: Listing Rules 3.1 – 3.1B* which states at section 7.3 (answer to question 6, 'What should be included in an announcement about a market-sensitive earnings surprise?'):
- 'If the earnings surprise relates to the entity's pcg earnings:*
- *a statement to the effect that the entity is expecting its earnings for the current reporting period to differ materially from its pcg earnings;*
  - *the amount of its pcg earnings;*
  - *...*
  - *if the announcement is made after the end of, and prior to the publication of its financial statements for, the reporting period, the amount or range of earnings it is expecting to report for the current reporting period;'*

### **Request for information**

Under Listing Rule 18.7 and having regard to the above, ASX asks PNV to respond separately to each of the following questions and requests for information:

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1. Does PNV 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. If the answer to question 1 is “no”, please advise the basis for that view.
  3. When did PNV first become aware of the Information?
  4. If the answer to question 1 is “yes” and PNV first became aware of the Information before the relevant date, did PNV 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 PNV was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps PNV took to ensure that the information was released promptly and without delay.
  5. In reference to the Appendices 3Y referred to in paragraphs C, D and E, Trading Policy and Listing Rule 12.12 please confirm the dealing disclosed in each Appendix 3Y complied with section 7 of the Trading Policy and if not, why not.
  6. In relation to the Trading Update, please provide clearer information as required by Guidance Note 8 highlighted at paragraph K as follows:
    - a) What the statement ‘*H1 FY21 up 31% on H1 FY20*’ is referring to (eg: revenue) and provide the H1 FY21 and H1 FY20 amounts.
    - b) The Q1 FY21 and Q1 FY20 amounts in the statement ‘*Strong sales Q1 FY21 up 75% on Q1 FY20*’.
    - c) Further detail to the statement ‘*Slower than expected sales in October and November*’ including amounts.
    - d) What the statement ‘*Q1 FY21 up 70% on Q1 FY20*’ is referring to (eg: revenue) and provide the Q1 FY21 and Q1 FY20 amounts.
    - e) What the statement ‘*Q2 FY21 up 16% on Q2 FY20*’ is referring to (eg: revenue) and also provide the Q2 FY21 and Q2 FY20 amounts.
    - f) What the statement ‘*1H FY21 up 41% on 1H FY21*’ is referring to (eg: revenue) and also provide the 1H FY21 and 1H FY21 amounts.
    - g) The revenue figures referred to in the statement ‘*YTD BARDA revenue lower than anticipated to the delay in obtaining our US FDA IDE approval. Recruitment of patients now scheduled for late Q3 FY21 and will be reflected in increased revenue*’.
  7. Please confirm that PNV is complying with the Listing Rules and, in particular, Listing Rule 3.1.
  8. Please confirm that PNV’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 PNV 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 Wednesday, 20 January 2021**. 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, PNV’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 PNV to request a trading halt immediately.

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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 PNV'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 PNV's securities under Listing Rule 17.3.

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

In responding to this letter, you should have regard to PNV'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 PNV'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**

We reserve the right to release a copy 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.

Regards

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**Melissa Kostopoulos**  
Compliance Adviser, Listings Compliance (Melbourne)