

# Market Announcement

2 April 2020

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## AstiVita Limited (ASX: AIR) – reinstatement to official quotation

ASX refers to the ASX market announcement dated 27 March 2020 (the ‘**Previous Announcement**’) regarding the suspension of AIR’s securities from official quotation, and to the announcements referred to therein.

AIR’s securities will be reinstated to official quotation at the commencement of trading on 3 April 2020 following the release:

- on 2 April 2020 of AIR’s announcement entitled “Retraction of Announcements” on the ASX market announcements platform (‘**MAP**’); and
- of this announcement on MAP, attaching AIR’s response to further queries from ASX.

ASX considers it to be appropriate and in the interests of an informed market to draw the market’s attention to the following:

1. As disclosed in its Previous Announcement, on 27 March 2020, ASX issued AIR with a second query letter in relation to the matters under enquiry. A copy of this letter is attached to this announcement.
2. ASX received AIR’s response to the second query letter on 31 March 2020.
3. On 1 April 2020, ASX informed AIR that the response was, in ASX’s opinion, not in a form suitable for release to the market, and asked AIR clarify its responses to certain questions from the second query letter.
4. On 2 April 2020, ASX received a further response from AIR, which included its answers to the questions put by ASX in the second query letter, together with the further questions asked by ASX on 1 April 2020 and its answers to those. A copy of this response is attached to this announcement.

### Issued by

**Adrian Smythe**

Manager, Listings Compliance (Sydney)



ABN 46 139 461 733

2 April 2020

### Response to Query Letter

Our Company has produced a complete timeline to the ASX on emails leading up to the Company's suspension, as part of its response to the Query Letter. At this time the ASX have refused to release this information to the market.

We highlight to the market Point C of the query letter from the ASX which clearly says "Where Possible" when we answer the queries below and we point out that all relevant information including the information contained in our ASX release and the attached patent continues to answer all the new ASX queries.

Please see our prior release to market on 26 March 2020.

*So, shareholders are aware, some of the questions raised by the ASX were technical in nature and in, the Board's view, only capable of answer by reference to the patent and the scientific papers referred to therein. It is not appropriate for the Company to attempt to summarise for the ASX matters of such a technical and scientific nature, at the risk of being accused of not effectively summarising the matter. The only appropriate response in the Board's view is to direct the ASX to the source documents where all the technical detail is available.*

The Board of AIR responds to the ASX query letter dated 27 March 2020 and further letter dated 1 April 2020 below as follows. We highlight to the market Point C of the query letter from the ASX which clearly says “Where Possible” when we answer the queries below and we point out that all relevant information including the information contained in our ASX release and the attached Patent Application continues to answer all of the new ASX queries. We continue to maintain that we have answered the questions according to the rules in your letters to the fullness of information currently available to the Board.

### **Question 1 – Query Letter**

In question 1b to the First Query Letter, ASX asked for specific details of how “highly progressed” the opportunity was at the time it was presented to AIR. AIR’s response was:

“As per previous ASX releases for AIR the company continues to develop personal care products.”

Further to ASX’s previous query, please answer the following:

- a. When Did ANO and / or AIR commence development of:
  - i. the invention which is the subject of the Patent Application; and
  - ii. the Patent Application.
- b. Please provide specific details of the stage of development of the Oral Care Products at the time it was presented to ANO, including whether AIR presented the results of any clinical studies supporting the safety and effectiveness of the product / information it brought to ANO’s attention?

### **Answer 1 – Query Letter**

- 1a. The Board of AIR has been clear to the market that they are developing a range of sunscreen and other cosmetic products with announcements made to market on
  - 31 May 2019
  - 28 August 2019
  - 25 October 2019
  - And recently on 28 February 2020

Oral care products are a natural extension of our future Dr Zinx product range and clearly belong to the category of personal care. AIR CEO is in the process of finalising the first Dr Zinx oral care product using ANO zinc with a European manufacturer. Joseph reached out to Dalia as part of this product development about an anti-viral product opportunity on Friday, 13 March 2020. Dalia commenced work on this research and patent on Saturday, 14 March 2020.

The idea for this invention started on Friday 13 March 2020 and the work on the patent commenced on Saturday, 14 March 2020. The draft patent was reviewed by our Intellectual Property ("IP") lawyers and filed by our IP lawyers on Tuesday afternoon. This is covered in our ASX release on Wednesday, 18 March 2020 which has not been released by the ASX.

Oral care products e.g. mouth spray do not require any approvals in the EU except for product registration based on the claims made on the label, regulation (EU) No 1223/2009 of the European Parliament and of the Council. This is in fact the same for the TGA as per the TGA email on Friday, 20 March 2020, "In accordance with the Therapeutic Goods (Excluded Goods) Determination 2018, made under Section 7AA of the Therapeutic Goods Act 1989, oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 of the Poisons Standard are considered to be exempt from regulation by the TGA". There are no Patent Application ingredients in the current formulation that are banned in the EU.

- 1b. Like many great inventions they start with ideas without any safety data or considerations around product effectiveness (e.g. like penicillin and 3M "post it notes", both discovered by accident). The CEO of AIR, Mr Joseph Mizikovsky, has a mandate to develop a range of personal care products and had been working on zinc-based product development initiatives including sunscreens for some time. Given the anti-bacterial properties and anti-viral properties of Zinc, the CEO came up with the oral care idea and reached out to ANO's chief scientist Dalia Mizikovsky who continued the research on Saturday, 14 March 2020. The culmination of this work resulted in the Patent Application which was notified to shareholders in the ANO ASX release along with the full patent attached on Wednesday, 18 March 2020, which the ASX did not release. Oral care products e.g. mouth spray do not require any approvals in the EU except for product registration based on the claims made on the label, regulation (EU) No 1223/2009 of the European Parliament and of the Council. This is in fact the same for the TGA as per the TGA email on Friday, 20 March 2020, "In accordance with the Therapeutic Goods (Excluded Goods) Determination 2018, made under Section 7AA of the Therapeutic Goods Act 1989, oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 of the Poisons Standard are considered to be exempt from regulation by the TGA". There are no Patent Application ingredients in the current formulation that are banned in the EU.

## Question 2 – Query Letter

In question 4 in the First Query Letter, ASX asked for an explanation as to the identity of the “present inventors” referred to on page 4 of the Patent Application. AIR’s response directed readers to the copy of the Patent Application sent to ASX on 18 March 2020, which did not disclose the names of the inventors, and had not been released to the market.

ASX has since come to understand that AIR’s CEO, Joseph Mizikovsky, and Dalia Mizikovsky are described as “Inventors” on IP Australia’s online record relating to the Patent Application.

Kindly confirm:

- a. the identity of the inventors noted above is correct;
- b. their relationships to ANO and its directors; and
- c. ANO’s understanding of their qualifications and experience in the research and development of anti-viral products for ingestion by human patients.

## Answer 2 – Query Letter

- 2a. The Board would like to enquire as why ASX is questioning the identities of the inventors given they are clearly stated on the patent application #2020900820. Nevertheless, the Board states that the people stated on the patent application #2020900820 are the inventors – Dalia Mizikovsky and Joseph Mizikovsky.
- 2b. The Board would like to enquire as why ASX is questioning the identities of the inventors given they are clearly stated on the patent application #2020900820. Nevertheless, they are obviously relatives of Mr Mizikovsky.
- 2c. AIR is not aware and does not believe this has any bearing on anything that could have a material effect on the company’s share price and the market as a whole. This looks akin to a fishing expedition by the ASX rather than seeking to elicit information which may be considered as genuinely having a material effect on the price of AIR’s securities. The Board attached the complete patent to our ASX release on 18 March 2020, which the ASX did not release.  
Please see our prior release to market on 26 March 2020.  
*So, shareholders are aware, some of the questions raised by the ASX were technical in nature and in, the Board’s view, only capable of answer by reference to the patent and the scientific papers referred to therein. It is not appropriate for the Company to attempt to summarise for the ASX matters of such a technical and scientific nature, at the risk of being accused of not effectively summarising the matter. The only appropriate response in the Board’s view is to direct the ASX to the source documents where all the technical detail is available.*

Nevertheless, we provide the following answers:

Dalia Mizikovsky – Bachelor of Advanced Science, majoring in Biomedical Science.

Currently completing her Honours in Developmental Biology at UQ (GPA 6.7) and has been employed by ANO since 17 April 2019.

Joseph Mizikovsky – has completed 2 subjects at the London School of Economics, and is currently studying a Bachelor of Business, majoring in marketing at QUT and has been employed by AIR since 26 September 2017.

In respect of most oral care products e.g. mouthwash, the products are not intended to be ingested in any significant quantities by humans.

Oral care products e.g. mouth spray do not require any approvals in the EU except for product registration based on the claims made on the label, regulation (EU) No 1223/2009 of the European Parliament and of the Council. This is in fact the same for the TGA as per the TGA email on Friday, 20 March 2020, "In accordance with the Therapeutic Goods (Excluded Goods) Determination 2018, made under Section 7AA of the Therapeutic Goods Act 1989, oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 of the Poisons Standard are considered to be exempt from regulation by the TGA". There are no Patent Application ingredients in the current formulation that are banned in the EU.

## **Question 2 – Further Letter 1 April 2020**

Re: question 2, attached to this email is a copy of the patent application submitted to ASX by the Company. The identity of the inventors is not mentioned in the application or in any of the material submitted by the Company for release to the market. The Company's responses to this question wrongly suggest otherwise.

## **Answer 2 – Further Letter 1 April 2020**

- 2a. The Board apologises and states that the people on the patent application #2020900820, as stated on the IP Australia website, are Dalia Mizikovsky and Joseph Mizikovsky.

### Question 3 – Query Letter

In questions 5, 6, 7 and 8 of the First Query Letter, ASX asked for an explanation of the evidence supporting various statements in the Patent Application and the Trading Halt Request regarding the expected operation of the invention, such as:

- “is expected to show anti-viral properties”;
- “could inhibit the replication of the novel coronavirus inside the cells of the oral cavity / mouth”; and
- “zinc ions derived from a zinc compound or a zinc salt inhibit the replication machinery of RNA viruses, and as such can help control illness and spread of the diseases”.

With respect to the queries regarding these statements, AIR’s response was:

“Refer to the research and patents listed in the Patent Application.”

Please provide a summary of the import of that research and other patents, and how it applies to the expected operation of the Oral Care Products in terms appropriate for release to the market and consistent with the statements of principle from the Code of Best Practice reproduced at paragraph D above.

### Answer 3 – Query Letter

3. Please see release to ASX on 18 March 2020, which was not released to market. *A standard organism feline coronavirus test of the product will be completed in approximately 3 weeks, by the UK based laboratory (MSL Solution Providers), at which stage AIR will confirm if the concept is successful against COVID-19. To test the efficacy of our product, we plan to conduct a test against the feline coronavirus to the EN Standard 14476:2013+A2:2019. Feline coronavirus is the globally accepted surrogate for COVID-19.*

Please see our prior release to market on 26 March 2020.

*So, shareholders are aware, some of the questions raised by the ASX were technical in nature and in, the Board’s view, only capable of answer by reference to the patent and the scientific papers referred to therein. It is not appropriate for the Company to attempt to summarise for the ASX matters of such a technical and scientific nature, at the risk of being accused of not effectively summarising the matter. The only appropriate response in the Board’s view is to direct the ASX to the source documents where all the technical detail is available.*

As far as the initial oral care products under the Dr Zinx brand are concerned, no claims will be made on the label. Until the initial testing has been completed in approximately 3 weeks, no final products where we want to make an anti-viral claim on the label will be made until regulatory approvals have been obtained.

The AIR Board is aware that when a patent is filed, it becomes publicly available information and shareholders and other interested parties can receive alerts on this information.

We did not want to be accused of not disclosing pertinent information in the event existing shareholders, prospective investors or other third parties placed value on this invention.

### **Question 3 – Further Letter 1 April 2020**

Re: question 3, being ASX's request for an explanation in appropriate language of the research and other patents cited in the patent application supporting statements about the expected operation of the invention, the Company has not responded to this request.

Firstly, the reference to the Company's intention to procure a "standard organism feline coronavirus test ... [to be] completed in approximately 3 weeks" does not relate to the prior research referred to in the patent application.

Secondly, the Company reiterates an earlier statement directing readers to the patent application and saying that it "is not appropriate ... to attempt to summarise for the ASX matters of such a technical and scientific nature." The Company has again not provided an answer to this question and, as such, it is unclear whether the Company has a reasonable basis for these statements. If the Company does not have a reasonable basis for making these statements, it should consider whether it is appropriate to revise or retract them.

Thirdly, the Company states that "[as] far as the initial oral care products under the Dr Zinx brand are concerned, no claims will be made on the label. Until the initial testing has been completed in approximately 3 weeks, no final products where we want to make an anti-viral claim on the label will be made until regulatory approvals have been obtained." It is unclear whether the Company is saying a) they intend or have taken steps to produce and sell certain Oral Care Products, regardless of the outcome of testing with respect to the application of the product to COVID-19, and b) whether it is after completion of the testing, or the receipt of regulatory approval, that it will "make an anti-viral claim on the label". Given that the Company announced its intention to submit a patent application with respect to the Oral Care Products on the basis of its possible effectiveness against COVID-19, and the patent application itself refers to COVID-19 as an application of the invention, ASX considers both matters require clarification, including the status of any arrangements to manufacture Oral Care Products, with or without anti-viral claims, and the regulatory approvals referred to.



### Answer 3 – Further Letter 1 April 2020

3a&b) The AIR Board confirms that the three statements referred to in the Query Letter are:

- “is expected to show anti-viral properties”  
Please see page 2 item 009 of the patent application #2020900820.
- “could inhibit the replication of the novel coronavirus inside the cells of the oral cavity / mouth”  
This is our clarification announcement of 17 March 2020  
*“The composition inhibits viral replication in the oral cavity through interacting with the replication machinery of the viruses.”*  
Please see page 9 Abstract of the patent application #2020900820  
The AIR Board confirms that novel coronavirus is in fact a virus in relation to these statements.
- “zinc ions derived from a zinc compound or a zinc salt inhibit the replication machinery of RNA viruses, and as such can help control illness and spread of the diseases”  
Please see page 4 item 0023 of the patent application #2020900820.

Again, in respect of all three statements the Board states.

*So, shareholders are aware, some of the questions raised by the ASX were technical in nature and in, the Board’s view, only capable of answer by reference to the patent and the scientific papers referred to therein. It is not appropriate for the Company to attempt to summarise for the ASX matters of such a technical and scientific nature, at the risk of being accused of not effectively summarising the matter. The only appropriate response in the Board’s view is to direct the ASX to the source documents where all the technical detail is available.*

- 3c) i) Oral care products e.g. mouth spray do not require any approvals in the EU except for product registration based on the claims made on the label, regulation (EU) No 1223/2009 of the European Parliament and of the Council. This is in fact the same for the TGA as per the TGA email on Friday, 20 March 2020, “In accordance with the Therapeutic Goods (Excluded Goods) Determination 2018, made under Section 7AA of the Therapeutic Goods Act 1989, oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 of the Poisons Standard are considered to be exempt from regulation by the TGA”. There are no Patent Application ingredients in the current formulation that are banned in the EU.  
AIR is in the process of ordering oral care products e.g. mouth spray, that falls under the above EU and TGA requirements and appropriate royalties to ANO to be finalised.

- ii) The AIR Board restates that no final products where we want to make an anti-viral claim on the label will be manufactured or ordered until regulatory approvals have been obtained for the specific markets in which we plan to sell the product.

#### Question 4 – Query Letter

With reference to AIR's response to question 12 of the First Query Letter and AIR's statement in the Draft Announcement that "[the] initial sales are contemplated on the Amazon EU platform as no regulatory approvals are needed", please:

- a. provide specific details of the development hurdles and requirements for approvals for sale of Oral Care Products (including the expected timeline for satisfaction of these hurdles and requirements) following completion of the "standard organism feline coronavirus test" to confirm the safety of the Oral Care Products for use internally by human patients and their effectiveness in treating or inhibiting COVID-19 in human patients; and
- b. explain the basis on which ANO believes that no regulatory approvals are required to sell the Oral Care Products on the Amazon EU platform, and why it considers that basis to be reasonable, given that it has not obtained legal advice with respect to the matter.

#### Answer 4 – Query Letter

- 4a. Please see release to ASX on 18 March 2020, which was not released to market.  
*A standard organism feline coronavirus test of the product will be completed in approximately 3 weeks, by the UK based laboratory (MSL Solution Providers), at which stage AIR will confirm if the concept is successful against COVID-19. To test the efficacy of our product, we plan to conduct a test against the feline coronavirus to the EN Standard 14476:2013+A2:2019. Feline coronavirus is the globally accepted surrogate for COVID-19.*  
Please see our prior release to market on 26 March 2020.  
*So, shareholders are aware, some of the questions raised by the ASX were technical in nature and in, the Board's view, only capable of answer by reference to the patent and the scientific papers referred to therein. It is not appropriate for the Company to attempt to summarise for the ASX matters of such a technical and scientific nature, at the risk of being accused of not effectively summarising the matter. The only appropriate response in the Board's view is to direct the ASX to the source documents where all the technical detail is available.*  
Once the initial results have been completed we will inform the market of these results and begin the commercialisation of the first Dr Zinx oral care product.

- 4b. Oral care products e.g. mouth spray do not require any approvals in the EU except for product registration based on the claims made on the label, regulation (EU) No 1223/2009 of the European Parliament and of the Council. This is in fact the same for the TGA as per the TGA email on Friday, 20 March 2020, "In accordance with the Therapeutic Goods (Excluded Goods) Determination 2018, made under Section 7AA of the Therapeutic Goods Act 1989, oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 of the Poisons Standard are considered to be exempt from regulation by the TGA". There are no Patent Application ingredients in the current formulation that are banned in the EU.

#### **Question 4 – Further Letter 1 April 2020**

Re: question 4, which asks for information about what development steps are required following completion of the "standard organism feline coronavirus test" to confirm the safety and effectiveness of the products for the use suggested, the Company's response largely repeats previous statements regarding forthcoming trials and research cited in the patent application. ASX infers from this answer that, following completion of the "standard organism feline coronavirus test", the Company does not intend to undertake any further testing before moving into production and sales. If that is the case, they should state that clearly for the benefit of the market.

#### **Answer 4 – Further Letter 1 April 2020**

The AIR Board restates their response in 4b) to this question. Oral care products e.g. mouth spray do not require any approvals in the EU except for product registration based on the claims made on the label, regulation (EU) No 1223/2009 of the European Parliament and of the Council. This is in fact the same for the TGA as per the TGA email on Friday, 20 March 2020, "In accordance with the Therapeutic Goods (Excluded Goods) Determination 2018, made under Section 7AA of the Therapeutic Goods Act 1989, oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 of the Poisons Standard are considered to be exempt from regulation by the TGA". There are no Patent Application ingredients in the current formulation that are banned in the EU.

The AIR Board restates that no final products where we want to make an anti-viral claim on the label will be manufactured or ordered until regulatory approvals have been obtained for the specific markets in which we plan to sell the product.

If we intend to make a claim, we will undertake testing for the specific market where we intend to sell the product as required by that regulator.

### Question 5 – Query Letter

With reference to AIR's response to question 13 of the First Query Letter, the "research and patents listed in the Patent Application" do not address whether the invention that is the subject of the Patent Application have been the subject of any trials for their effectiveness in inhibiting COVID-19.

Please disclose, then, whether AIR is or is not aware of whether the invention that is the subject of the Patent Application has been the subject of trials for the inhibition of COVID-19 in human patients.

### Answer 5 – Query Letter

5. Please see release to ASX on 18 March 2020, which was not released to market. *A standard organism feline coronavirus test of the product will be completed in approximately 3 weeks, by the UK based laboratory (MSL Solution Providers), at which stage AIR will confirm if the concept is successful against COVID-19. To test the efficacy of our product, we plan to conduct a test against the feline coronavirus to the EN Standard 14476:2013+A2:2019. Feline coronavirus is the globally accepted surrogate for COVID-19.*

The patent was attached to this announcement in full.

Please see our prior release to market on 26 March 2020.

*So, shareholders are aware, some of the questions raised by the ASX were technical in nature and in, the Board's view, only capable of answer by reference to the patent and the scientific papers referred to therein. It is not appropriate for the Company to attempt to summarise for the ASX matters of such a technical and scientific nature, at the risk of being accused of not effectively summarising the matter. The only appropriate response in the Board's view is to direct the ASX to the source documents where all the technical detail is available.*

### Question 5 – Further Letter 1 April 2020

Re: question 5, which asks again for information regarding trials conducted of the product(s) in question, the Company again repeats previous statements regarding forthcoming trials and research cited in the patent application. ASX infers from this answer that the Companies are not aware of any such trials. If that is the case, they should state that clearly for the benefit of the market.

#### **Answer 5 – Further Letter 1 April 2020**

*The AIR Board restates A standard organism feline coronavirus test of the product will be completed in approximately 3 weeks, by the UK based laboratory (MSL Solution Providers), at which stage AIR will confirm if the concept is successful against COVID-19. To test the efficacy of our product, we plan to conduct a test against the feline coronavirus to the EN Standard 14476:2013+A2:2019. Feline coronavirus is the globally accepted surrogate for COVID-19.*

It is clear that our invention will be tested in approximately the next three weeks. Tests will be conducted to comply with labelling requirements for the market in which we intend to sell the products.

#### **Question 6 – Query Letter**

Please confirm that AIR's responses to the questions above have been authorised and approved by its board.

#### **Answer 6 – Query Letter**

The AIR Board confirms that the responses to the questions above have been authorised and approved by the AIR Board.

The AIR Board confirms that this suspension has caused significant hours and administration costs for Directors and staff. The Board continues to reserve all of its rights and on behalf of its shareholders and will again invite ASX to lift suspension and reinstate trading of the company's securities.

Authorised by:  
Geoff Acton  
Non-executive Director



27 March 2020

Reference: 16052

Mr Geoff Acton  
Director  
AstiVita Limited  
1821 Ipswich Road  
Rocklea QLD 4106

By email

Dear Mr Acton

**AstiVita Limited ('AIR'): query letter**

ASX refers to:

- A. ASX's letter to AIR issued at around 3:27pm on 19 March 2020 (the 'First Query Letter') regarding recent and proposed announcements by AIR, including:
- a. AIR's announcement entitled "Trading Halt", released on the ASX market announcements platform ('MAP') on 16 March 2020 (the 'Trading Halt Request'), concerning its request for a trading halt and disclosing that:
    - i. AIR had brought to the attention of Advance NanoTek Limited ('ANO') a "highly progressed opportunity regarding the development of oral care products (New Products) [the 'Oral Care Products'] which could prevent the coronavirus cells multiplying."
    - ii. The reason for the trading halt was "to seek legal advice in respect of IP Ownership" with respect to the Oral Care Products.
    - iii. AIR understood that ANO intended to file a patent application with respect to the Oral Care Products on 17 March 2020;
  - b. AIR's announcement, released on MAP on 17 March 2020, titled "Clarification on Trading Halt Letter"; and
  - c. AIR's draft announcement entitled "Antiviral Composition for Oral Care Patent # 2020900820" lodged with ASX on 18 March 2020 (the 'Draft Announcement'), and attaching a patent application (the 'Patent Application').

The First Query Letter included the following statements:

- *"This request is made under listing rule 18.7."*<sup>1</sup>
- *"ASX reserves the right to release a copy of this letter and your response on MAP under listing rule 18.7A. Accordingly, your response should be in a form suitable for release to the market."*(emphasis added)

- B. AIR's response to the First Query Letter, received by ASX at 4:43pm on 19 March 2020 and released on MAP on 27 March 2020.

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<sup>1</sup> Listing rule 18.7 provides that "[an] entity must give ASX any information, document or explanation that ASX a) asks for to enable ASX to be satisfied that the entity is, and has been, complying with, or will comply with, the listing rules or any conditions or requirements imposed under the listing rules; or b) reasonably requires to perform its obligations as a licensed market operator.

- C. Section 4.15 of ASX Listing Rules Guidance Note 8 - Continuous Disclosure: Listing Rules 3.1-3.1B, headed "Guidelines on the contents of announcements under Listing Rule 3.1", and which provides:

*"Wherever possible, an announcement under Listing Rule 3.1 should contain sufficient detail for investors or their professional advisers to understand its ramifications and to assess its impact on the price or value of the entity's securities. ...*

*An announcement under Listing Rule 3.1 must be accurate, complete and not misleading. To not be misleading, opinions expressed in an announcement should be honestly held and balanced and should be clearly identified as a statement of opinion rather than a statement of fact. Any forward looking statements in an announcement must also have a reasonable basis in fact or else by law they will be deemed to be misleading. Entities should note ASIC's guidance that any material assumptions or qualifications that underpin forward looking statements in an announcement under Listing Rule 3.1 should be stated in the announcement. ASX also encourages the inclusion of material assumptions and qualifications as it provides context and will help the market to understand the basis for the forward looking statements.*

*Entities should not use an announcement under Listing Rule 3.1 as a guise to publish material that is really promotional, political or tendentious in nature rather than being information that a reasonable person would expect to have a material effect on the price or value of its securities. ...*

*Finally, an announcement must be couched in language that is appropriate for release to the market. It should be factual, relevant and expressed in a clear and objective manner. Emotive, intemperate or defamatory language should not be used, nor should vague or imprecise terms such as "single digit" or "double digit", which do not allow investors to assess the value of the information for the purpose of making an investment decision."*<sup>2</sup>

- D. Section 4.1 "Research and development" of the Code of Best Practice for Reporting by Life Sciences Companies (second edition) published May 2013 (the 'Code of Best Practice'), which states:

*"When releasing information on a product, which is the subject of research, companies need to ensure that it is fair and accurate, and that it provides balance in presenting and addressing the commercial prospects for the product."*<sup>3</sup>

#### Questions and requests for information

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

1. In question 1b to the First Query Letter, ASX asked for specific details of how "highly progressed" the opportunity was at the time it was presented to AIR. AIR's response was:

*"As per previous ASX releases for AIR the company continues to develop personal care products."*

Further to ASX's previous query, please answer the following:

- a. When did ANO and / or AIR commence development of:
  - i. the invention which is the subject of the Patent Application; and
  - ii. the Patent Application.
- b. Please provide specific details of the stage of development of the Oral Care Products at the time it was presented to ANO, including whether AIR presented the results of any clinical studies

<sup>2</sup> Statements of equivalent import are also included in ASX Listing Rules Guidance Note 14 – ASX Market Announcements Platform.

<sup>3</sup> [https://www.asx.com.au/documents/research/Code\\_of\\_Best\\_Practice\\_for\\_Reporting\\_by\\_Life\\_Science\\_Companies.pdf](https://www.asx.com.au/documents/research/Code_of_Best_Practice_for_Reporting_by_Life_Science_Companies.pdf), page 8.

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supporting the safety and effectiveness of the product / information it brought to ANO's attention?

2. In question 4 in the First Query Letter, ASX asked for an explanation as to the identity of the "present inventors"<sup>4</sup> referred to on page 4 of the Patent Application. AIR's response directed readers to the copy of the Patent Application sent to ASX on 18 March 2020, which did not disclose the names of the inventors, and had not been released to the market.

ASX has since come to understand that AIR's CEO,<sup>5</sup> Joseph Mizikovsky, and Dalia Mizikovsky are described as "Inventors" on IP Australia's online record relating to the Patent Application.<sup>6</sup>

Kindly confirm:

- a. the identity of the inventors noted above is correct;
  - b. in the case of Ms Mizikovsky, their relationships to AIR and its directors; and
  - c. AIR's understanding of their qualifications and experience in the research and development of anti-viral products for ingestion by human patients.
3. In questions 5, 6, 7 and 8 of the First Query Letter, ASX asked for an explanation of the evidence supporting various statements in the Patent Application and the Trading Halt Request regarding the expected operation of the invention, such as:
- "is expected to show anti-viral properties";
  - "could inhibit the replication of the novel coronavirus inside the cells of the oral cavity / mouth"; and
  - "zinc ions derived from a zinc compound or a zinc salt inhibit the replication machinery of RNA viruses, and as such can help control illness and spread of the diseases".

With respect to the queries regarding these statements, AIR's response was:

*"Refer to the research and patents listed in the Patent Application."*

Please provide a summary of the import of that research and other patents, and how it applies to the expected operation of the Oral Care Products in terms appropriate for release to the market and consistent with the statements of principle from the Code of Best Practice reproduced at paragraph D above.

4. With reference to AIR's response to question 12 of the First Query Letter and AIR's statement in the Draft Announcement that "[the] initial sales are contemplated on the Amazon EU platform as no regulatory approvals are needed", please:
- a. provide specific details of the development hurdles and requirements for approvals for sale of Oral Care Products (including the expected timeline for satisfaction of these hurdles and requirements) following completion of the "standard organism feline coronavirus test" to confirm the safety of the Oral Care Products for use internally by human patients and their effectiveness in treating or inhibiting COVID-19 in human patients; and
  - b. explain the basis on which AIR believes that no regulatory approvals are required to sell the Oral Care Products on the Amazon EU platform, and why it considers that basis to be reasonable, given that it has not obtained legal advice with respect to the matter.

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<sup>4</sup> The First Query Letter inadvertently used the term "current inventors" instead of "present inventors".

<sup>5</sup> AIR's announcement entitled "Management Restructure, released on MAP on 31 May 2019.

<sup>6</sup> <http://pericles.ipaustralia.gov.au/ols/auspat/applicationDetails.do?applicationNo=2020900820>, accessed on 26 March 2020.



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5. With reference to AIR's response to question 13 of the First Query Letter, the "research and patents listed in the Patent Application" do not address whether the invention that is the subject of the Patent Application have been the subject of any trials for their effectiveness in inhibiting COVID-19.

Please disclose, then, whether AIR is or is not aware of whether the invention that is the subject of the Patent Application has been the subject of trials for the inhibition of COVID-19 in human patients.

6. Please confirm that AIR's responses to the questions above have been authorised and approved by its board.

**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 9:00 am AEST on Wednesday, 1 April 2020.

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, AIR'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.

ASX reserves the right to release a copy of this letter and your response on MAP under listing rule 18.7A.

Accordingly, your response should be in a form suitable for release to the market. Your response should be sent to me by e-mail. 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 MAP.

Yours sincerely

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**Neel Bhowmick**  
Adviser, Listings Compliance (Sydney)