

20 May 2020

### **Response to Query Letter**

We are in receipt of a query letter from the ASX on Monday, 18 May 2020, based on our announcement to market on Monday morning 18 May 2020.

The Board has responded to each of ASX's queries below but would also like to emphasise the following:

- Nothing in the Announcement seeks to suggest validation of the patent. Our announcement refers to the results supporting the underlying science behind the patent, which is that a combination of zinc and hinokitiol inhibits the growth of viruses.
- Nothing in the Announcement suggests that the product tested is a cure for any virus or that it has an effect similar to a vaccine. So the ASX is aware, like hand sanitiser, the product is a preventative measure only to inhibit the growth of a virus.
- Regarding the "standard v non-standard" discrepancy, MSL did conduct a standard test, the non-standard reference is to the organism used in the tests, being an organism grown in the lab (Munich strain) and in respect of which there is no other comparable organism (hence it being "non-standard").
- Regarding the written consent of MSL for publication of its Report, on 12 May 2020, MSL was informed that that the Results would be released to the to the market as soon as they were received (email attached). The response received from MSL on 14 May 2020 and delivery of the final report was in the Board's view tacit approval for this to occur.

The Board of ANO responds to the ASX query letter dated 18 May 2020 below as follows.

### **Question 1**

Specifically what product was supplied to MSL for testing?

### **Answer 1**

Generic mouth spray combined with a percentage of our invention the subject of the patent application (which for clarity includes hinokitinol), was supplied to MSL for testing.

### **Question 2**

Who supplied the product to MSL for testing?

### **Answer 2**

Antaria Pty Ltd, which is 100% owned subsidiary of Advance NanoTek Limited ("ANO"), prepared the samples in its approved TGA licenced facility.

### **Question 3**

Please explain why the name of the product and the batch number and expiry date for the product tested by MSL in the MSL Report are shown as "N/S" and how that accords with testing best practice.

### **Answer 3**

The product was a single preparation prepared in the Antaria approved TGA licenced facility. It was not part of a batch production process nor does it have an expiry date that would identify the product, hence the non identification of the product.

Aside from this we cannot explain how / why MSL handle their reporting formats for products. Please see that the appearance of the product, described as turbid liquid and is in line with the mouth spray product provided to MSL.

#### **Question 4**

Please explain why the customer shown on the MSL Report is Antaria rather than ANO or Astivita Limited ("AIR") and describe what role it performs in manufacturing or supplying the product tested by MSL.

#### **Answer 4**

Antaria Pty Ltd is 100% owned subsidiary of Advance NanoTek Limited. Antaria has two GMP licences for manufacturing as per ANO's website and two approved TGA laboratories.

#### **Question 5**

Please describe the relationship Antaria has with ANO and/or AIR.

#### **Answer 5**

As per answer 4 above Antaria is 100% owned subsidiary of Advance NanoTek Limited.

#### **Question 6**

What steps did AIR or Antaria take to ensure the provenance of the product supplied to MSL for testing?

#### **Answer 6**

As per answer 2, the product was prepared in Antaria's TGA approved laboratory.

#### **Question 7**

Has AIR or Antaria received written approval from MSL to release the MSL Report on MAP? If so, please provide a copy to ASX (not for release to the market).

#### **Answer 7**

On 12 May 2020, MSL was informed that that the Results would be released to the market as soon as they were received (email attached). The response received from MSL on 14 May 2020 was in the Board's view tacit approval for this to occur.

### Question 8

Has AIR or Antaria requested that MSL retain the sample product tested for longer than 2 months? If not, why not?

### Answer 8

We have not requested the sample be held for longer than one month. We could prepare further samples in Antaria's approved TGA laboratory if we wish to conduct further tests.

### Question 9

Noting:

- a. that the products in question have been described by AIR as for oral care (see recital B above);
- b. the patent application describes the products as for use in the oral cavity (see recital C above); and
- c. the comments in the MSL Report to the effect that the European Standard governing the conditions of the test applies to disinfection (including hygienic hand-rub, instrument disinfection, and surface disinfection),

please explain in terms suitable for release to the market the basis for AIR's conclusion that the results confirm "the underlying science in the patent application", commenting specifically on the extrapolation from the virucidal action when in contact with external surfaces for up to an hour, to the virucidal effect in an oral care product.

### Answer 9

The Report also refers to "antiseptic" products.

*"The standard method BS EN 14476 describes a test method and the minimum requirements for virucidal activity of a chemical disinfectant and antiseptic products that form a homogenous physically stable preparation when diluted with hard water – or in the case of ready to use products that are not diluted when applied, - with water. Products can only be tested at a concentration of 80% (97% with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substances. This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection."*

The proposed application of the invention is in mouth spray and mouth wash and other oral care products. It is accepted that these are effective antiseptic products and there are currently many products on the market advertising their antiseptic capabilities. Dr ZinX mouth spray will be like these other products currently sold on the market.

ANO interprets the section of the Report regarding disinfectants which has been focussed on by ASX as a confirmatory statement that the European Standard applied to the tests undertaken applies to products used in the medical area in the fields of hygienic handrub etc. This however is not a statement intended to preclude the standard as being applied to antiseptic products such as oral hygiene products.

#### **Question 10**

Apropos AIR's previous statements that the test to be undertaken would be the "standard organism feline coronavirus test" (see recital B above), please explain in terms suitable for release to the market the significance of the reference in the MSL Report to a "nonstandard organism feline coronavirus", described there as a "Deviation from [the] Standard Method", to:

- a. the claims made in the patent application; and
- b. AIR's previous statements to the market regarding the expected efficacy of the oral care products against COVID-19.

#### **Answer 10**

MSL did conduct a standard test, the non-standard refers to the organism used in the test, being an organism grown in the lab (Munich strain) and in respect of which there is no other comparable organism (hence it being "non-standard").

To address the ASX's broader questions, AIR announced on 17 March 2020

*"The patent is looking at a range of oral care products that could inhibit the replication of the novel coronavirus inside the cells of the oral cavity / mouth"*

AIR confirms the following:

- A feline coronavirus test has been conducted under European Standard EN14476.
- The feline coronavirus, strain Munich was used.
- The results show the test product received has achieved a 4-log reduction against Feline coronavirus when tested under the condition stipulated in this report, with a 1-hour contact time.

AIR is satisfied that the report and its conclusions support the previous statement made on 17 March 2020.

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

Authorised by:

Geoff Acton

Non-executive Director

18 May 2020

Reference: 18384

Mr Geoff Acton  
Managing Director  
Astivita Limited

By email

Dear Mr Acton

**Astivita Limited ("AIR")**

ASX refers to:

- A. the announcements released by AIR on the ASX market announcements platform ("MAP") on 16 March 2020,<sup>1</sup> which included the following statements:

*"AIR is, a customer of ANO and recently brought to the attention of ANO a highly progressed opportunity regarding the development of oral care products (New Products), which could prevent the coronavirus cells multiplying. ANO has informed AIR that it intends to file a patent application in respect of the New Products on Tuesday, 17 March 2020."*

- B. AIR's response dated 2 April 2020 to ASX's query letter dated 27 March 2020, released on MAP on 2 April 2020, which reproduced the following statement (emphasis added):<sup>2</sup>

*"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."*

- C. the patent application provided by AIR with respect to the invention, released on MAP on 27 March 2020,<sup>3</sup> which included the following statements:

- i. *"The present invention relates to the field of anti-viral products for the oral cavity. Specifically, it relates to an anti-viral composition which can be widely used in oral care products for the prevention and treatment of viral infections."*
- ii. *"The composition of the present invention is expected to show anti-viral properties. The composition of the present invention is suitable for use in oral care products, such as, but not limited to, mouth rinse, toothpaste, gargling solutions and mouth wash. In other embodiments, the composition may comprise a throat lozenge or a nasal spray or a topical oral mucosa treatment composition or a topical nasal mucosa treatment or an inhaler or puffer or a treatment for the oro-pharynx. Products containing this composition may be used continuously and frequently, for the prevention and treatment of viral infections."*

- D. the proposed announcement submitted by AIR for release on MAP on 18 May 2020, which states (emphasis added):

*"AIR has received the report from MSL Solution Providers in London on Saturday and the results are **in line with the Board's expectations confirming the underlying science in the patent application (#2020900820)** jointly owned with Advance NanoTek Limited. The two Boards are looking to*

<sup>1</sup> <https://www.asx.com.au/asxpdf/20200316/pdf/44g31kbycj4spl.pdf>

<sup>2</sup> <https://www.asx.com.au/asxpdf/20200402/pdf/44gng0qz286t9g.pdf>, particularly the answers to questions 3, 4a, and 5.

<sup>3</sup> <https://www.asx.com.au/asxpdf/20200327/pdf/44ggnv0w7j1v0q.pdf>

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commercialise the first product using zinc and hinokitiol, the subject of the patent application, which the Companies intend to market in Europe through Amazon UK. The Board is unable to predict the impact to revenue from royalties and the success of the product at this very early stage until the product is released, and do not expect this to have a material effect on the results in FY2020. The complete report from MSL Solutions Providers are [sic] attached along with the related research article from the Medical University of Vienna.”

- E. the following statements from the report by Microbiological Solutions Limited (“MSL”) presented from pages two to 10 of the proposed announcement, headed “Study Title: Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step 1)” (the “MSL Report”) (emphasis added):

i. “Scope

*The standard method BS EN 14476 describes a test method and the minimum requirements for virucidal activity of **a chemical disinfectant and antiseptic products** that form a homogenous physically stable preparation when diluted with hard water – or in the case of ready to use products that are not diluted when applied, - with water. Products can only be tested at a concentration of 80% (97% with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substances. **This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.***

***This European standard applies to areas and situations where disinfection is medically indicated.** Such indication occurs in patient care, for example: In hospitals, in community medical facilities and in dental institutions or in clinics of schools, of kindergartens and of nursing homes, and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for patients.”*

ii. “Outline of Test Method (Obligatory Test Conditions)

*A sample of the test product is diluted in synthetic hard water in products diluted at point of use or water in the case of ready to use products is added to a test suspension of viruses in a solution of interfering substance. The mixture is maintained at one of the temperatures and contact times specified in the standard. At the end of this contact time, an aliquot is taken; the virucidal action in this portion is immediately suppressed by a validated method (dilutions of the sample in ice-cold cell maintenance medium). The dilutions are transferred into cell culture units either using monolayer or cell suspension. Infectivity tests are done either by plaque test or quantal tests. After incubation, the titres of infectivity are calculated according to Spearman and Käber or by plaque counting. Reduction of virus infectivity is calculated from differences of Ig virus titres before (virus control) and after treatment with the product.”*

iii. “Deviations from Standard Method

*1 – The product was **tested against nonstandard organism Feline coronavirus**; therefore reference inactivation controls were not performed due to no acceptance criteria available.”*

iv. “Test Result Summary

*The test product received has achieved a 4-log reduction against Feline coronavirus when tested under the condition stipulated in this report, **with a 1-hour contact time.**”*

ASX notes that the customer shown on page 1 of the MSL Report is Antaria Pty Ltd (“Antaria”) and that on page 3 of the MSL Report, under the heading “Test information”, Antaria is named as the manufacturer and supplier of the product.



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On page 1 of the MSL Report, there is a disclaimer that: “The test results on this report refer only to the items tested as supplied by the customer. This report shall not be reproduced except in full and with written approval of Microbiological Solutions Ltd. All reports are archived for a minimum of 2 years. The sample will be retained for 1 month unless otherwise requested in writing.

In addition, on page 3 of the MSL Report, under the heading “Test information”, the name of the product being tested and the batch number and expiry date are both specified as “N/S”, which ASX assumes means “not supplied” or something similar.

- F. The *Code of Best Practice for Reporting by Life Sciences Companies* (second edition) published May 2013 (the “Code of Best Practice”), which includes the following guidance:

*“Companies should be conscious that most investors will have very limited or no understanding of the science underlying the company’s activities, and may have difficulty comprehending the company’s announcements. It is important, therefore, to make announcements in terms that facilitate evaluation of the significance of the information being reported.”*

#### Questions and requests for information

Having regard to the above, and in the interests of providing sufficient information to the market on which investors can make suitably-informed decisions, ASX asks ANO to respond separately to each of the following questions and requests for information:

1. Specifically what product was supplied to MSL for testing?
2. Who supplied the product to MSL for testing?
3. Please explain why the name of the product and the batch number and expiry date for the product tested by MSL in the MSL Report are shown as “N/S” and how that accords with testing best practice.
4. Please explain why the customer shown on the MSL Report is Antaria rather than ANO or Astivita Limited (“AIR”) and describe what role it performs in manufacturing or supplying the product tested by MSL.
5. Please describe the relationship Antaria has with ANO and/or AIR.
6. What steps did AIR or Antaria take to ensure the provenance of the product supplied to MSL for testing?
7. Has AIR or Antaria received written approval from MSL to release the MSL Report on MAP? If so, please provide a copy to ASX (not for release to the market).
8. Has AIR or Antaria requested that MSL retain the sample product tested for longer than 2 months? If not, why not?
9. Noting:
  - a. that the products in question have been described by AIR as for oral care (see recital B above);
  - b. the patent application describes the products as for use in the oral cavity (see recital C above); and
  - c. the comments in the MSL Report to the effect that the European Standard governing the conditions of the test applies to disinfection (including hygienic hand-rub, instrument disinfection, and surface disinfection),

please explain in terms suitable for release to the market the basis for AIR’s conclusion that the results confirm “*the underlying science in the patent application*”, commenting specifically on the extrapolation from the virucidal action when in contact with external surfaces for up to an hour, to the virucidal effect in an oral care product.

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10. Apropos AIR's previous statements that the test to be undertaken would be the "standard organism feline coronavirus test" (see recital B above), please explain in terms suitable for release to the market the significance of the reference in the MSL Report to a "nonstandard organism feline coronavirus", described there as a "Deviation from [the] Standard Method", to:
- the claims made in the patent application; and
  - AIR's previous statements to the market regarding the expected efficacy of the oral care products against COVID-19.

**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 Thursday 21 May 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 and may require ANO to request a trading halt immediately.

ASX reserves the right to release a copy of this letter and your response on the ASX Market Announcements Platform 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 at [neel.bhowmick@asx.com.au](mailto:neel.bhowmick@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 MAP.

**Enquiries**

If you have any queries or concerns about any of the above, please contact me immediately.

Yours sincerely

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