

21 March 2022

Ms Alice Montefiore-King
Adviser, Listings Compliance (Sydney)
ASX Limited

By email

Response to ASX query letter dated 16 March 2022

We refer to your letter dated 16 March 2022, and respond as follows (using the terminology ASX has adopted in your letter):

1. Does ADO consider the following to be information that a reasonable person would expect to have a material effect on the price or value of its securities:

a) the Manufacturing Difficulties Information?

No

b) the Sales Information?

No

c) the European Clinical Trial Information?

No

d) the Regulatory Issues Information?

No

2. If the answer to any of questions 1 a), b), c) or d) above is 'no', please advise the basis for that view.

Manufacturing Difficulties Information

The basis for that view at paragraph 1(a) above by AnteoTech Limited (**AnteoTech**) is set out below:

- AnteoTech has made it clear in prior announcements that manufacturing is not a straight-forward process, as issues arise from time to time. The ordinary course of in vitro diagnostic (IVD) scale-up manufacture does not follow a linear path, involves some unpredictability, involves challenges including quality optimisation and quality control and, inevitably requires refinement. The comments provided in the webinar were merely intended to provide an update on the most recent issues that had been experienced and that AnteoTech was now close to resolving.

- AnteoTech refers to its Quarterly Business Update for the period ending 31 December 2021 [released on ASX on 1 February 2022] which:
 - made it clear that IVD supply is heavily regulated and that in order to operate successfully organisations must ensure the consistent manufacture of product of the highest quality and performance. AnteoTech specifically noted that:

“Any questionable aspect of quality or support will risk scrutiny by regulatory authorities whilst in market and this could lead to penalties and/or removal of product from the market. Many organisations close to AnteoTech have been the subject of such scrutiny and have been forced to remove product batches or entire products from the market and this has caused the organisation valuable reputational damage that will hinder further developments.”
 - made reference to challenges in scaling up (which are common to IVD scale-up manufacture):

“Nano technology is a complex science with many variables. Scaling up the technology to produce a product with enough volume to supply a market can be a difficult process due the number of variables that can cause issues. Since April 2021 we have been gradually scaling production at Operon and have resolved issues relating to supplier material variations, batch quality of supplied particle, interface issues between Operon produced product and Axxin produced product. These types of issues are very common in IVD manufacturing, and we often use our close relationships with Operon, Ellume and other manufacturers to discuss issues and share resolution pathways.

It is inevitable that manufacturing will encounter difficulties in the future due to the many variables at play. However, having committed the effort of the last eight months we are now confident that our product can be produced at the scale required to support a large volume of sales.”
 - states:

“We have worked in partnership with Operon to identify several steps that can be optimised during the manufacturing process to secure maximum output. We are now working with Operon to implement these steps to ensure scale-up manufacturing processes are optimal for maximum capacity production runs. Separately, we continued quality testing across product batches with actual samples during the quarter.”

Sales Information

The basis for that view at paragraph 1(b) above is set out below:

- Given the dynamic nature of the regulatory landscape and the need to ensure optimal manufacturing processes, AnteoTech has not provided any sales forecast for EuGeni nor shown any EuGeni related sales in any announcements (including its Appendix 4C and 4D and Interim Financial Reports), or otherwise provided any specific guidance as to time to market – nor is it prudent for AnteoTech to do so.
- AnteoTech is ensuring that quality controls are in place while at the same time pursuing regulatory and government (e.g. EU Common List) approvals in its chosen markets, which must be achieved prior to commencing sales.

- The subject of regulatory and government approvals has been addressed in prior announcements on ASX:

- The Chairman in his address at the 2021 AGM [released on ASX on 11 November 2021] advised:

“Regulatory processes are now the focus, converting our CE approval to the different applicable requirements of each country in order to allow local sales to occur.”

- The Chairman’s address, the CEO presentation and verbal presentation at the 2021 AGM [released on ASX on 11 November 2021] are linked to AnteoTech’s webpage. In the CEO presentation Mr Thomson outlined AnteoTech’s strategy towards market entry with a new IVD product in the light of changing regulatory conditions and the need to protect AnteoTech’s reputation to produce high quality products:

“IVD manufacture and distribution is one of the most highly regulated industries in the world. Regulatory requirements have increased dramatically at regional, country and jurisdictional levels during the pandemic and we have invested heavily to meet that challenge in the form of a now fully resourced Quality management team and regulatory resources. Our challenge is to leverage this capability to produce the required material for approvals including trials, at all jurisdictional levels but with particular focus on the larger regulatory requirements associated with the FDA in the US and the new IVDR regulations being implemented in Europe.

In the diagnostics industry reputation is everything. We must first ensure that our products can be trusted. Failure to do this will undo all other work we have completed. We must focus on providing the product to market utilising all quality processes to protect us from negative perceptions. Once achieved, trust in product will lead to advocacy and we seek new leading expert opinion that supports our products claims and can be used as leverage to further market entry. Provision of marketing capability focusing on EuGeni’s differentiators rounds out a set of market position elements that will drive sales into the segments that we target.”

- AnteoTech’s Quarterly Business Update for the period ending 31 December 2021 [released on ASX on 1 February 2022] contained several statements touching on the process to market:

“As a response to the ongoing evolution of variants and a need to ensure test performance standards are maintained, governments worldwide continue to set the quality bar higher by increasing the regulatory requirements for market entry and continued market participation. In Europe, this has manifested in broader adoption of the EU Common List for procurement of RATs in varied segments. In Australia, the TGA has adopted a guidance note from the European Commission’s Medical Device Co-ordination Group (MDCG) on the clinical performance evaluation of RATs. The MDCG requirements underpin the new European In Vitro Diagnostic Regulations (IVDR) that focus on test efficacy using prospective sampling in the 0 – 7 days post-onset symptoms range. A prospective trial involves the recruitment of patients for direct harvesting of samples to be tested on the EuGeni platform for SARS-CoV-2 Ag RDT.

The TGA has advised us we must add prospective clinical data to support our test performance claims generated using stored samples to align our technical data with the MDCG guidelines. We are currently collecting this data via trials in Australia and Europe,

which will also provide the required data set for entry to the EU Common List and IVDR registration.

To be able to confidently supply a volume of product into any market, a legal manufacturer must integrate three primary elements being Manufacturing, Distribution and Quality Management. Any scaled selling of product carries considerable commercial risk if the integration of these elements is not robust. Whilst we recognise that there has been a significant and immediate imperative to turn on sales to support the Life Science business, we have balanced our progression to ensure we also protect long term security of the business....”.

- AnteoTech’s Appendix 4D and Interim Financial Report for the half year ended 31 December 2021 [released on ASX on 24 February 2022] also referred to the dynamic nature of the regulatory environment:

The regulatory landscape continues to shift, with Europe overlaying additional requirements, solely for COVID RAT’s. Locally, regulatory authorities have expanded their requirements through the period. As a company we have responded to the changes with increased organisational capability and identified the need for additional clinical trial data to meet the revised regulatory requirements. The Life Sciences team is highly focussed on driving these trials to completion in a manner that addressed the current regulatory requirements to allow full market access across our target markets.

European Clinical Trial Information

The basis for that view at paragraph 1(c) is set out below:

- The design of a clinical trial and its subsequent implementation is a specialised area. To be able to conduct a clinical trial internal and external expertise is required including the services of a Clinical Research Organisation (**CRO**), such as the Spanish CRO in AnteoTech’s case. Establishing the requirements for such a trial is a complex and detailed exercise that must occur before any patients are tested.
- AnteoTech has provided detail in its prior announcements as to the processes and requirements involved with various clinical trials:
 - AnteoTech in its the Quarterly Business Update for the period ending 31 December 2021 [released on ASX on 1 February 2022] stated:

“The TGA has advised us we must add prospective clinical data to support our test performance claims generated using stored samples to align our technical data with the MDCG guidelines.”

“.... In December, the TGA contacted AnteoTech to indicate that additional clarification information relating to planning for Variants of Concern.

The additional information was compiled and submitted to the TGA in January. Following a review of the additional information, the TGA has requested further clinical data be provided, together with other aspects of information. At the time of writing, AnteoTech was working through the details of the request with the TGA to determine

the expected timeframe needed to gather the additional information and fulfil the conditions of the TGA's guidelines."

"Opportunities to procure the required member state sponsorship and run an efficient clinical trial in Europe were progresses during the Quarter, although strong competition exists for access to hospitals and clinics to run the trials."

"The Italian pharmacy RAT service targeted by AnteoTech's distributor Exxe requires EU Common List registration for participation. We will fulfil this requirement by running a clinical trial in Spain via the Spanish clinical research organisation AKRN."

- AnteoTech's TGA Registration Update (3) [released on ASX on 10 February 2022] states:

"AnteoTech has had ongoing and constructive discussions with the TGA over the past week. These discussions focussed on the reconciliation of AnteoTech's dataset, which includes stored and direct patient samples, and the TGA's requirements for additional clinical evidence. Following these discussions, it has been concluded that AnteoTech's proposed approach of conducting new clinical trials represents the most expeditious pathway to meeting these data requirements."

The data generated from these trials will ensure that a new submission by AnteoTech will meet the TGA's regulatory requirements, as well as providing the Company with data for additional regulatory approval processes, including registration for the EU Common List. The trials will also provide further evidence of performance relating to new variants of concern listed by the World Health Organisation ("WHO"), lower limit of detection and other performance measures from a vaccinated population."

By undertaking a new submission, AnteoTech has the flexibility and opportunity to compile the new clinical data from studies in Australia and Europe and present this as a fresh and unencumbered submission to the TGA."

AnteoTech will provide updates as key milestones are achieved."

- It is noted that Therapeutic Goods Administration (**TGA**), World Health Organisation (**WHO**), European Commission Medical Device Co-ordination Group (**MDCG**), and EU Common List guidelines are publicly available documents. The processes and systems for conducting clinical IVD trials are publicly available, and not unique to AnteoTech's trials. Undertaking any clinical trial involves the establishment of trial protocols, selection of sites, ethics approvals and patient recruitment. The expected timeframes of such trials always have an element of uncertainty. This uncertainty has been evidenced previously by AnteoTech when delays due to change in COVID infection levels impacted a clinical trial being undertaken in India. AnteoTech included under the heading "Sample Use Case Validation Ongoing" as part of the AnteoTech announcement "AnteoTech appoints SE Asia Distributor" released on ASX platform on July 19, 2021:

"AnteoTech anticipated results from the evaluation in line with the initially indicated timeline of June 2021; however, the significant decrease of COVID-19 incidents in India has meant this is likely to take several more weeks to obtain sufficient data to evaluate efficacy. The timing of results and further updates to shareholders will be dependent on obtaining enough positive samples to clearly evaluate the test."

- The update provided in the webinar was an update on progress in the above areas. The comment made in response to the question regarding the clinical trial in Spain reflected timeframes typical of a clinical trial process of this type.

Regulatory Issues Information

The basis for that view at paragraph 1(d) above is set out below:

- As referenced earlier and seen from extracts of prior market announcements referred to above, AnteoTech is working within a dynamic regulatory environment, which is constantly evolving. Addressing regulatory matters by AnteoTech occurs in the usual and ordinary course of business given the market in which the EuGeni product is to be distributed.
- Within the registration process it is not uncommon to encounter matters raised by regulatory bodies that are new or otherwise not apparent, which are then worked through in the ordinary course via an iterative process with the relevant body to resolve points raised.
- The “Regulatory Issues Information” was provided as a response to a question on those countries and is consistent with the changing and dynamic regulatory environment that AnteoTech is navigating.
- AnteoTech’s Quarterly Business Update for the period ending 31 December 2020 stated:

“Low COVID-19 case numbers in Australia have made access to validated positive COVID-19 patients for the purposes of a prospective clinical trial more challenging. In response, we have pursued clinical trial activities in association with VIDRL using stored patient samples. These samples are stored in dilution using Viral Transfer Media (VTM), which can cause signal interference with the test. The VTM cannot be removed in this clinical trial setting and is not present in the normal intended use of the test. i.e., direct patient sampling.”

Note: VIDRL is the Victorian Infectious Diseases Reference Laboratory.

- AnteoTech’s Quarterly Business Update for the period ending 30 September 2021 [released on ASX on 28 October 2021] described the dynamic regulatory environment in relation to country registration and guidance on timeframes for country registrations:

“At the start of the COVID-19 pandemic, few countries required a rigorous process to register a SARS-CoV-2 rapid test once a test had received a CE mark. As a result of a vast number of tests requesting authority to enter the market, some of low-quality health authorities of individual countries have been compelled over the past six months to implement more rigour when assessing the appropriateness of a particular test to be supplied in their country. Today, virtually every country requires a registration process irrespective of the registration status of the test in another country. These processes are constantly being reviewed, and changes to the requirements are made regularly.

There are countries that the Company intends to operate in that require processes ranging from a review of our technical data through to a full clinical trial in a government-operated laboratory. These processes can require up to a 12-month time frame to achieve registration.

For all European countries adhering to the European Directive 98/79/EC (IVDD), CE marking is a prerequisite before any country registration can occur. As reported previously, most

distributors in Europe will not undertake any discussions before the CE mark has been attained, and most European countries will not allow registration to begin until a local distributor is appointed.

Frustratingly, the evolution of these additional processes now makes country registration a serial process that consumes go-to-market time.

Generically, the key steps to enter a market include:

- 1. Appoint a local distributor (legally required in most countries)*
- 2. Register Local Legal Agent (this can be the distributor, but must be a locally registered entity)*
- 3. Submit Regulatory Dossier:*
 - 3.a Translation of all documentation*
 - 3.b Notarisation/ Legalisation of Documents*
- 4. Clinical Evaluation as required by:*
 - 4.a Ministry of Health / Regulator*
 - 4.b Distributor &/or Customer*
- 5. Application Processing and Review*
- 6. Product Registration*
- 7. Commence Marketing*
- 8. Import Licence Application”*

- AnteoTech’s Appendix 4D and Interim Financial Report for the half year ended 31 December 2021 [released on ASX on 24 February 2022] also made it clear that:

“The regulatory landscape continues to shift, with Europe overlaying additional requirements, solely for COVID RAT’s. Locally, regulatory authorities have expanded their requirements through the period. As a company, we have responded to these changes with increased organisational capability and identified the need for additional clinical trial data to meet the revised regulatory requirements. The Life Science team is highly focused on driving these trials to completion quickly in a manner that addresses the current regulatory requirements to allow full market access across our target markets.”

- In the AnteoTech announcement AnteoTech Secures EuGeni Distribution Agreement for Greece and Cyprus [released on ASX on 16 September 2021] it is noted:

“Since the recent signing of the Distributor Agreements with Biomed Global (Thailand, Malaysia, Indonesia, Vietnam, Singapore, Myanmar), Apacor (UK), Unison (Philippines), and Pera Medikal (Turkey), AnteoTech, together with the distributors, is now completing the regulatory requirements to register the EuGeni reader and test in their respective territories. Regulatory requirements are becoming more rigorous in many jurisdictions so that tests that are unable to meet the standards set are restricted from these markets.

Regulatory approvals often require independent clinical assessments for each of the multiple regulatory bodies. Once this process has been completed our distributors can commence selling the EuGeni platform in their markets and each approval will be announced as it is secured.”

3 When did ADO first become aware of:

- a) the Manufacturing Difficulties Information (including any part thereof)?**
- b) the Sales Information?**
- c) the European Clinical Trial Information (including any part thereof)?**
- d) the Regulatory Issues Information (including any part thereof)?**

Your response should specify the relevant dates.

a) the Manufacturing Difficulties Information (including any part thereof)?

Manufacturing scale-up commenced in April 2021. Various issues in the course of the scale-up have arisen and been addressed as they occur. The issue concerning particle aggregation arose in December 2021 and was considered to be a normal operational issue arising from scaling up of manufacturing that was capable of being resolved in a short period of time. It is noted that manufacturing issues/optimisation are not uncommon during manufacturing design and scale-up and, as has previously been noted in AnteoTech's announcements, are identified and are dealt with as they occur.

b) the Sales Information?

It is not a case of first becoming aware of the Sales Information. Sales will result in countries targeted by AnteoTech once regulatory and government approvals in those countries are achieved.

c) the European Clinical Trial Information (including any part thereof)?

It is not a question of when AnteoTech first became aware of European Clinical Trial Information as the establishment of a clinical trial is an incremental and staged process. Discussions commenced with the Spanish CRO in January 2022.

d) the Regulatory Issues Information (including any part thereof)?

As advised earlier, it is standard business practice to address numerous matters raised by regulatory authorities in the usual and ordinary course of achieving regulatory approvals.

The swab registration issue in Turkey was brought to AnteoTech's attention in November 2021.

The issue referred to in Asia, regarding some trials with government organisations about market entry using stored samples, was brought to AnteoTech's attention in December 2021. The issue with the use of stored samples and AnteoTech's test is not new and has previously been advised to the market. AnteoTech became aware in December 2020 that viral transfer media (VTM) may cause interference in a stored sample trial which was notified to the market in AnteoTech's Quarterly Business Update for the period ended 31 December 2020. AnteoTech is working with Asian regulatory bodies to register the test using different methods where possible.

Advice concerning AnteoTech's registration process in the UK by the Medicines and Healthcare products Regulatory Agency for additional data was received in February 2022.

- 4. If the answer to any of questions 1 a), b), c) or d) above is 'yes' and ADO first became aware of the relevant information before 10 March 2022, did ADO make any announcement prior to the relevant date which disclosed the relevant information? If so, please provide details. If not, please explain why the relevant information was not released to the market at an earlier time, commencing specifically on when you believe ADO was obliged to release the relevant information under Listing Rules 3.1 and 3.aA and what steps ADO took to ensure that the relevant information was released promptly and without delay.**

Not applicable

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

AnteoTech confirms that it considers that it is complying with the Listing Rules, including Rule 3.1.

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

The responses above have been approved by the Board of AnteoTech.

By Order of the Board
AnteoTech Limited

Tim Pritchard
Company Secretary



16 March 2022

Reference: 49065

Mr Tim Pritchard
Company Secretary
Anteotech Limited
Unit 4, 26 Brandl Street
Eight Mile Plains QLD 4113

By email

Dear Mr Pritchard

AnteoTech Limited ('ADO'): Query letter

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

- A. ADO's announcement titled 'Investor Update Webinar Invitation' released on the ASX Market Announcements Platform ('MAP') on 8 March 2022 advising of a webinar to be held on 10 March 2022 at 12pm AEST/1pm AEDT with ADO's CEO, Mr Derek Thomson.
- B. ADO's announcement titled 'InvestorStream Interview Presentation' released on MAP at 2:13pm AEDT on 10 March 2022 ('**Presentation Announcement**').
- C. The change in the price of ADO's securities on 10 March 2022 from 17.0 cents at the open of trading to a low of 9.7 cents and a closing price of 10.5 cents, and the significant increase in the volume of ADO's securities traded on that day.
- D. ASX's price query letter dated 10 March 2022 and ADO's response dated 11 March 2022, released together on MAP at 9:23am AEDT on 11 March 2022, which included the following questions (in bold) and answers:

'1. Does ADO consider that the information disclosed within the Presentation explains the recent trading in ADO's securities? If the answer to this question is "yes", please explain the basis for this view and why the Presentation was not marked price sensitive.'

Information disclosed within the presentation may explain the recent trading in ADO securities. However, the presentation was an update on progress of previously announced activities and, as such, was not viewed as price sensitive.

2. Was anything material discussed at the Webinar that was not disclosed within the Presentation? If so, please provide the details.

ADO does not believe anything material was discussed in the Webinar that was not commented on in previous announcements and updates. However, to ensure full market knowledge and disclosure, ADO will lodge an announcement with a link to the Webinar on the ASX platform.

3. Is ADO aware of any information concerning it that has not been announced to the market which, if known by some in the market, could explain the recent trading in its securities?

ADO is not aware of any other information.

...

5. If the answer to question 3 is "no, is there any other explanation that ADO may have for the recent trading in its securities?

As responded to above, ADO will lodge an announcement with a link to the Webinar on the ASX platform to enable complete disclosure to the market. ADO views there is general market

uncertainty causing a dislocation in equity markets with increased volatility and as a result heightened perception of risk.

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

ADO confirms it is in compliance with the Listing Rules.'

- E. ADO's announcement titled 'Investor Webinar Link' released on MAP at 9.54am on 11 March 2022 containing a link to a webpage to access a recording of the webinar held at 1pm AEDT on 10 March 2022 ('Webinar').

ASX observes that ADO presented a slide at the Webinar titled 'Events Since Last Update' (reproduced below) which was not included in the Presentation Announcement and disclosed, inter alia, that manufacturing scale-up difficulties had been encountered in the Life Sciences division.

EVENTS SINCE LAST UPDATE



Since the last Investor Update the key events that have taken place include:

Life Sciences

- TGA submission feedback received
- Regulatory requirements have tighten market entry
- Engaged Clinical Research Organisations to for clinical trials
- Manufacturing scale-up difficulties encountered
- Pierre Nathie and Ian Steinhardt strengthen marketing team
- Design freeze COVID-19 Flu A / Flu B

Energy

- Demonstrated stability of AnteoX combined with most prevalent industry binder – SBR binder
- AnteoX results replicated in full cell performance testing showing increased capacity retention
- AnteoTech micro silicon anode prototype achieves improved key cycle life results milestone

ASX also observes that following information was disclosed by ADO's CEO during the Webinar:

(i) Manufacturing difficulties

When speaking to the fourth dot point in the slide reproduced above ('Manufacturing scale-up issues encountered') at the 4-5 minute mark of the Webinar, Mr Thomson stated (emphasis added):

'We have recorded some minor manufacturing scale-up issues even prior to November such as QR code reading issues requiring implementation of laser QR code printing on cassettes. More recently, we have discovered some particle aggregation issues in larger scaled-up batches.

These events are quite common in lateral flow development and scale-up. They do however require us to manage our quality very tightly and when they occur we must quarantine product before it is released and complete root cause analysis in order that mitigations can be implemented.

This process delays our manufacturing and sales of product significantly but again must be completed to maintain quality and ensure our manufactured product is as designed.

We believe that most of the manufacturing issues are now known and should be behind us very very soon.'

Mr Thomson also stated the following at around the 15 minute mark:

'We now believe that all changes to the test are known and we will complete these changes prior to the upcoming clinical trials in Europe.'

(together the **'Manufacturing Difficulties Information'**)

(ii) Sales - EuGeni Reader and SARS CoV-2 Ag Rapid Diagnostic Test

Mr Thomson stated the following at around the 27 minute mark in response to the question, 'What is the dollar value of the COVID/EuGeni sales so far?' (emphasis added):

'I couldn't tell you. It is very low. We haven't been able to target selling opportunities directly because of the manufacturing issues that I have mentioned that have held us up, and so it is very low, very low at the moment.'

(the **'Sales Information'**)

(iii) European clinical trial

Mr Thomson stated the following in relation to the European clinical trial (emphasis added):

- At around the 16 minute mark:

'... These conditions make it difficult to collect prospective samples from patients in order to meet criteria such as required categories of days post onset of symptoms, or percentage of samples above a Ct threshold.

We are designing our trials to fulfil as much of the requirements as we can. However, we cannot exclude the need to review the data we are collecting and/or change or add trials in order to meet the regulatory requirements that we target.'

- At around the 35 minute mark in response to the question, 'Has the clinical trial in Spain begun, and what date do you expect this to finish?':

'The clinical trial in Spain has not begun to take patient samples yet. There is quite a bit of design and lead-in work that needs to be undertaken to set up the trial, and we are going through that process now.

Our target is the April/May sort of timeframe to start taking patient samples and usually these trials take about 3-4 months to complete – so that gives you some guidance of the timeframes that we are talking about.'

- At around the 44 minute mark: 'We are looking at a 4 month trial.'

(together the **'European Clinical Trial Information'**)

(iv) Regulatory issues

Mr Thomson stated the following in relation to regulatory issues at around the 29 minute mark (emphasis added):

'We have had regulatory issues as I outlined in the presentation in other areas.

Turkey, for example, we were almost through to a government based trial for entry into the market when we discovered that our swab supplier didn't have Turkish registration and that was a requirement. So we have to wait until they do get Turkish registration. So that has held us up there.

In Asia, we have been going through some trials with government organisations about market entry using stored samples, and those stored samples are housed or protected in a

viral transport media, which doesn't work with our test. So we are working through those issues currently to see how we could go through a different process in most of the Asian countries.

In the UK, we were about half way through a process in the UK when they brought on a new requirement for some cross-reactivity testing that we hadn't completed at the Doherty [Institute]. So we are going to complete that cross-reactivity testing as part of our current trials in Europe.

So different answers for different markets. It is a very complex system generally of regulatory approvals and then each country has their own requirements ...'

(the 'Regulatory Issues Information')

- F. The change in the price of ADO's securities on 11 March 2022 from 10.0 cents at the open of trading to a low of 9.2 cents and a closing price of 9.4 cents, and the significant increase in the volume of ADO's securities traded on that day.
- 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.'*

Questions and Request for information

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

1. Does ADO consider the following to be information that a reasonable person would expect to have a material effect on the price or value of its securities:
 - a) the Manufacturing Difficulties Information?
 - b) the Sales Information?
 - c) the European Clinical Trial Information?
 - d) the Regulatory Issues Information?
2. If the answer to any of questions 1 a), b), c) or d) above is 'no', please advise the basis for that view.
3. When did ADO first become aware of:
 - a) the Manufacturing Difficulties Information (including any part thereof)?
 - b) the Sales Information?
 - c) the European Clinical Trial Information (including any part thereof)?
 - d) the Regulatory Issues Information (including any part thereof)?Your response should specify the relevant dates.
4. If the answer to any of questions 1 a), b), c) or d) above is 'yes' and ADO first became aware of the relevant information before 10 March 2022, did ADO make any announcement prior to the relevant date which disclosed the relevant information? If so, please provide details. If not, please explain why the relevant information was not released to the market at an earlier time, commenting specifically on when you believe ADO was obliged to release the relevant information under Listing Rules 3.1 and 3.1A and what steps ADO took to ensure that the relevant information was released promptly and without delay.
5. Please confirm that ADO is complying with the Listing Rules and, in particular, Listing Rule 3.1.
6. Please confirm that ADO'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 ADO 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 **9:30am AEDT on Monday, 21 March 2022**. 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, ADO'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 ADO to request a trading halt immediately.

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 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 ADO'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 ADO's securities under Listing Rule 17.3.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to ADO'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 ADO'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.

Yours sincerely

Alice Montefiore-King
Adviser, Listings Compliance (Sydney)