

**BIOLIDICS LIMITED**  
(Company Registration Number: 200913076M)

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**RESPONSE TO SGX QUERIES – ANNOUNCEMENTS IN RELATION TO  
APPOINTMENT OF AYTU BIOSCIENCE, INC. AND US MARKET UPDATE**

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The board of directors (the "**Board**" or the "**Directors**") of Biolidics Limited (the "**Company**" or "**Biolidics**") refers to the (i) announcement in relation to the appointment of Aytu Bioscience, Inc. (NASDAQ: AYTU) ("**Aytu**") as an exclusive distributor for the Company's rapid test kits for the Novel Coronavirus 2019 antibodies in the United States of America ("**USA**") on 23 April 2020 (the "**Aytu Appointment Announcement**"), and (ii) announcement in relation to the US market update on 28 June 2020 (the "**US Market Update Announcement**").

Further to the above-mentioned announcements, the Board wishes to provide the following additional information in response to the queries raised by the Singapore Exchange Securities Trading Limited ("**SGX-ST**") on 30 June 2020.

Unless otherwise defined, capitalised terms used in this announcement in the Company's responses shall have the same meaning as ascribed to them in the Aytu Appointment Announcement and the US Market Update Announcement.

**Question 1**

**Noted that Aytu had a binding commitment to purchase an initial 500,000 COVID-19 Antibody Test Kits by 24 April 2020. How many COVID-19 Antibody Test Kits have Biolidics supplied to Aytu to date?**

*Company's response:* As at the date of the US Market Update Announcement, the Company has delivered 13,000 COVID-19 Antibody Test Kits to Aytu.

**Question 2**

**Can Biolidics confirm if Aytu has fulfilled the binding commitment to purchase an initial 500,000 COVID-19 Antibody Test Kits by 24 April 2020, and Biolidics is able to record the full revenue from the supply of the 500,000 COVID-19 Antibody Test Kit under the binding commitment? If no, please explain the deviation(s) from the binding commitment.**

*Company's response:* Aytu had placed an order and made a deposit for 500,100 COVID-19 Antibody Test Kits in accordance with the terms of the Distribution Agreement by 24 April 2020. As at the date of the US Market Update Announcement, the Company recorded revenue for the 13,000 COVID-19 Antibody Test Kits delivered to Aytu. As set out in the US Market Update Announcement, the revenue from such sales is not material on the earnings per share and net tangible assets per share of the Group for the financial year ending 31 December 2020 ("**FY2020**").

As set out in the US Market Update Announcement, pursuant to the terms of the Termination Agreement, the Company is obligated to process a full refund in favour of Aytu for all deposits paid by Aytu with respect to all undelivered orders of the COVID-19 Antibody Test Kits. As such, the Company has made a full refund for all deposits paid by Aytu with respect to all undelivered orders of the COVID-19 Antibody Test Kits. In accordance with the Singapore Financial Reporting Standards (International) ("**SFRS(I)**"), the Company has not recognised revenue for the undelivered COVID-19 Antibody Test Kits.

**Question 3**

**As a result of the Termination Agreement, will Biolidics be receiving any return of the COVID-19 Antibody Test Kits from Aytu? If yes, what is Biolidics' estimate of the returns, do the returns pertain to the initial 500,000 COVID-19 Antibody Test Kit under the binding commitment, and what does Biolidics intend to do with the returns?**

Company's response: Under the terms of the Termination Agreement, Aytu will return the 13,000 COVID-19 Antibody Test Kits to the Company and the Company is not required to make a refund to Aytu for these returned test kits. The Company intends to distribute the COVID-19 Antibody Test Kits returned by Aytu to other markets outside of the US.

#### **Question 4**

**As a result of the Termination Agreement, the Company is obligated to process a full refund in favor of Aytu for all deposits paid by Aytu with respect to undelivered orders of the test kits. What is the quantum of the refund and how material is this to the Company?**

Company's response: In view of the commercial sensitivity of pricing information and in consideration of the intense competition for serology test kits globally, the Company will not be able to disclose the quantum of the refund to Aytu for the test kits which have not been delivered to Aytu. Further, in Aytu's announcement released on 27 June 2020 in relation to the Non-Binding LOI and the Distribution Agreement, there was no mention of the quantum of the refund and the Company is of the view that the same level of information should be in the public domain.

In accordance with the SFRS(I), the deposit received from Aytu resulted in an increase in cash holdings of the Group with a corresponding increase in liability (which represents a prepayment from a customer). The Company has not recognised revenue for the deposits paid by Aytu with respect to undelivered orders of the COVID-19 Antibody Test Kits. The refund of this prepayment to the Group will result in a decrease in cash (asset) and an equivalent decrease in prepayment (liability), with no impact on the income statement. Additionally, the Company had cancelled the orders placed with the contract manufacturer in relation to the undelivered test kits and the Company has received a full refund from the contract manufacturer. Accordingly, the refund to Aytu will not have any material impact on the earnings per share and net tangible assets per share of the Group for FY2020.

#### **Question 5**

**Please elaborate on the considerations that led to Biolidics' acceptance of the Agreement cancellation terms in the Termination Agreement, including whether there were any form of compensation to Biolidics or Aytu for the termination. Please also provide the rationale for the termination, as well as whether Biolidics considered the possibility of keeping and enforcing the Agreement, while pursuing the Proposed Collaboration concurrently.**

Company's response: The Company had considered the following factors, before its acceptance of the Distribution Agreement cancellation terms:

- a. At the time of the Company's acceptance of the Distribution Agreement cancellation terms, there was no certainty and visibility on a timeline when the COVID-19 Antibody Test Kits will be granted an authorisation under the US FDA Emergency Use Authorisation ("EUA") under the then prevailing FDA Serology Test Policy. The Company believed that the US government's approach to the balancing of risks and benefits in relation to serology test kits has shifted from where it was in mid-March 2020 and correspondingly, the US FDA has tightened rules on serology tests. As announced on 2 July 2020, the Company had applied to the US FDA to voluntarily withdraw its application for EUA pursuant to the FDA Serology Test Policy and noted from the US FDA website that the COVID-19 Antibody Test Kits are no longer listed on the notification list under the FDA Serology Test Policy. It is noteworthy that as at 26 June 2020, as published on the US FDA website, there are approximately 50 serology test kits that are no longer on the notification list and approximately 180 serology test kits still pending EUA authorisation;
- b. Increased competition in the US market for serology test kits since the Company entered into the Distribution Agreement. As at 26 June 2020, as published on the US FDA website, the Company understands that there are over 190 different serology test kits in the US offered by various manufacturers and approximately 11 serology test kits have obtained EUA; and
- c. There is a ready demand for the Company's COVID-19 Antibody Test Kits in Asia.

Other than the refund of the previously paid deposits, there is no cash compensation paid or payable to either party for the termination. Under the terms of the Termination Agreement, the parties agreed to, among other things, a mutual release of claims.

The Company did consider the possibility of enforcing the Distribution Agreement while pursuing the Proposed Collaboration concurrently. Following much deliberation and discussions with Aytu, both parties mutually agreed to streamline resources to focus on the Development Project and FDA authorisation of a new product which we believe would see a wider application including point-of-care use outside of clinical settings. We believe this may offer better commercial opportunities for both companies.

#### **Question 6**

**What due diligence and market analysis did the Board conduct when it applied to the US FDA for approval to distribute the test kits in the USA in April 2020? What has changed in the 2 months since then resulting in the terminating of the Agreement to sell the test kits in the USA, and withdraw its application with the US FDA?**

*Company's response:* In deciding to apply for a listing of the COVID-19 Antibody Test Kits under the FDA Serology Test Policy in April 2020, the Board had considered the following factors:

- a. The potential size of the market given the rising number of COVID-19 cases globally in April 2020; and
- b. The speed with which, we believed at the time, the COVID-19 Antibody Test Kits could have been introduced into the US market under the then prevailing FDA Serology Test Policy.

However, the Board noted that since April 2020, the number of serology test kits which have been permitted under the FDA Serology Test Policy for distribution in the US market have increased significantly from approximately 50 to more than 190 as at the date of the US Market Update Announcement. Many of these test kits offered by competitors are sold at lower prices compared to the Company's COVID-19 Antibody Test Kits. Further, the use of the Company's current COVID-19 Antibody Test Kits, like those offered by other manufacturers, is limited to testing in laboratories or by healthcare workers at the point-of-care.

The Company believes offering a serology test kit with broader use and applications outside the laboratory or clinical settings (for example, by individuals at home) in the US market may present a better commercial opportunity for the Company compared to the current COVID-19 Antibody Test Kits, which are meant for use only in laboratories or by healthcare workers at the point-of-care. As such, having considered the foregoing, the Company decided to (a) re-focus its efforts and resources as it relates to the US market to undertake the Development Project with the aim of developing a new COVID-19 test kit for the detection of the Novel Coronavirus 2019 antibodies with broader use and applications in various settings compared to the current COVID-19 Antibody Test Kits; and (b) withdraw the current COVID-19 Antibody Test Kits from the US market at this time.

#### **Question 7**

**Can Biolidics provide updates on the Section 510(k) application in the US, and Biolidics' plans for the application and results of the application?**

*Company's response:* As set out in the Aytu Appointment Announcement, Aytu was obligated under the Distribution Agreement to complete and obtain regulatory clearance for the COVID-19 Antibody Test Kits under Section 510(k) (the "**Section 510(k) Application**") in order to retain its role as Biolidics' exclusive distributor of the COVID-19 Antibody Test Kits in the USA for the remainder of the term of the Distribution Agreement. As of the date of the US Market Update Announcement, Aytu had not commenced the Section 510(k) Application, although the Company noted that the clinical trial plan which forms part of the Section 510(k) Application had been prepared by Aytu. Owing to the rapidly evolving nature of the COVID-19 situation, the US market for serology test kits has undergone significant changes in the last few weeks. Competition in the US market for serology test kits has

increased significantly in recent weeks. As a result, the Company has decided not to pursue the Section 510(K) Application in the US for the current COVID-19 Antibody Test Kits.

#### **Question 8**

**Biolidics announced plans to refocus efforts and resources on a new joint development project, in collaboration with Aytu, to develop a new test kit with broader use and applications in various settings compared to the current test kit. Who is driving the Development Project and what is the potential investment / capital injection expected from Biolidics?**

*Company's response:* Biolidics and Aytu will be driving the Development Project together. As set out in the US Market Update Announcement, the parties have entered into the Non-Binding LOI for the proposed collaboration on the Development Project pursuant to which the Company and Aytu have agreed to negotiate the terms of a binding definitive agreement regarding the Proposed Collaboration. As such, as at the date of this announcement, the Company is not able to estimate the potential investment/capital injection required. The Company will make the appropriate announcement(s) when there is further material development relating to the Development Project and/or the Proposed Collaboration.

#### **Question 9**

**With regards the Development Project which it intends to conduct in collaboration with Aytu, please elaborate on the considerations and reasons for the Board deciding to do so with Aytu. Did the Board consider other companies before deciding to enter into such a collaboration with Aytu, and why?**

*Company's response:* The Company had considered other companies for such a collaboration, drawing on past experience collaborating with other companies on the joint development of new products. However, the Company has decided on pursuing the Proposed Collaboration with Aytu in view of the following:

- a. Biolidics and Aytu have established a working relationship;
- b. Both parties have already laid out a preliminary proposed execution plan, have mutually identified potential clinical as well as potential technology partners for the Section 510(k) Application clinical trials required to generate real-world data to support the Section 510(k) Application registration process with the FDA for the proposed new test kit; and
- c. Prior to entering into the Distribution Agreement, the Company had performed due diligence regarding Aytu, and identified the various merits and limitations of Aytu before the appointment of Aytu as the Company's US distributor.

As such, the parties have entered into the Non-Binding LOI for the proposed collaboration on the Development Project pursuant to which the Company and Aytu have agreed to negotiate the terms of a binding definitive agreement regarding the Proposed Collaboration. The Company will make the appropriate announcement(s) when there is further material development relating to the Development Project and/or the Proposed Collaboration.

**BY ORDER OF THE BOARD**

**Yee Pinh Jeremy**  
**Non-Executive Non-Independent Chairman**  
**3 July 2020**

*This announcement has been prepared by Biolidics Limited (the "Company") and has been reviewed by the Company's sponsor, United Overseas Bank Limited (the "Sponsor"), for compliance with Rules 226(2)(b) and 753(2) of the Singapore Exchange Securities Trading Limited (the "SGX-ST") Listing Manual Section B: Rules of Catalyst. This announcement has not been examined or approved by the SGX-ST. The SGX-ST assumes no responsibility for the contents of this announcement, including the correctness of any of the statements or opinions made or reports contained in this announcement.*

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