

BIOLIDICS LIMITED
(Company Registration Number: 200913076M)

**RESPONSE TO SGX QUERIES – ANNOUNCEMENTS IN RELATION TO BIOLIDICS’
RAPID TEST KITS FOR THE DETECTION OF NOVEL CORONAVIRUS 2019**

The board of directors (the “**Board**” or “**Directors**”) of Biolidics Limited (the “**Company**” and together with its subsidiaries, the “**Group**”) refers to the following announcement and press releases (the “**Announcements**”) in relation to the Company’s rapid test kits for the detection of the Novel Coronavirus 2019:

S/No.	Title of Announcement / Press Release	Date
1	General Announcement: SIGNING OF MANUFACTURER AGREEMENT FOR RAPID TEST KITS TO DETECT NOVEL CORONAVIRUS 2019	30 March 2020
2	General Announcement: PRESS RELEASE: BIOLIDICS TO LAUNCH ITS RAPID TEST KIT FOR COVID-19; OBTAINS APPROVAL FROM SINGAPORE’S HEALTH SCIENCES AUTHORITY FOR ITS RAPID TEST KIT TO BE USED IN SINGAPORE	30 March 2020
3.	General Announcement: RAPID TEST KIT FOR COVID-19 APPROVED FOR USE BY THE FOOD AND DRUG ADMINISTRATION OF THE PHILIPPINES	1 April 2020
4	General Announcement: PRESS RELEASE: RAPID TEST KIT FOR COVID-19 OBTAINS CE MARKING FOR USE IN THE EUROPEAN UNION	6 April 2020

Further to the 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 1 April 2020, 3 April 2020, 4 April 2020 and 8 April 2020.

Question 1

When was the manufacturer agreement (“**Agreement**”) entered into?

Company’s response: The manufacturing agreement was signed on 21 March 2020.

Question 2

When was the provisional authorization from Singapore’s Health Sciences Authority (HSA) received? Is this considered material information that ought to be announced?

Company’s response: The provisional authorization from HSA was received on 27 March 2020 (Friday). The Board is of the opinion that the materiality lies not with the approval from HSA or manufacturer agreement alone but from having the ability to commercialize the product (with the product liability in place) and an indicative date of availability of the product (which was disclosed in the announcement).

Question 3

To provide the Board's views and justifications, on why the receipt of HSA Approval was not announced on or around 20 Mar / 24 Mar / 27 Mar, despite this information being publicly announced by HSA on or around 20 Mar and 24 Mar 2020?

Company's response: We wish to clarify that the provisional authorization received by Biolidics Limited (the "Company") from HSA on 20 March 2020 was in relation to the Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit (the "Vazyme Product"), which is a product manufactured by Nanjing Vazyme Biotech Co., Ltd ("Nanjing Vazyme").

The Company only obtained approval on 27 March 2020 for the product to be manufactured and marketed under its own brand, the Biolidics 2019-nCoV IgG/IgM Detection Kit (the "Biolidics Test Kits"), hence it could not announce any earlier.

The Company does not know why the HSA had stated that the name of the test that obtained the provisional authorization is "Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit also marketed as Biolidics 2019-nCoV IgG/IgM Detection Kit". Similarly, the Company does not know why the HSA Regulatory Update was published on 24 March 2020, before the approval of the Biolidics Test Kits which was obtained on 27 March 2020. The Company intends to clarify with the HSA.

The Company believes that the receipt of the HSA approval for the Biolidics Test Kits became material only when it is certain that the Company could commercialize the Biolidics Test Kits. The Company believed that this required an executed manufacturing agreement, HSA approval and product liability insurance coverage which it executed/obtained on 21, 27 and 30 March 2020 respectively.

As the Company only intended to commence production and commercialization of the Biolidics Test Kits upon procurement of the product liability insurance, the Board believes that an announcement on the receipt of the HSA approval with no certainty of commercialization may be misleading to shareholders and potential investors.

Question 4

In light of the seriousness of the Covid-19 situation and where there is a world-wide shortage of Covid-19 test kits, what are the Board's considerations in assessing if obtaining of the HSA approval is material information that warrants immediate disclosure?

Company's response: The Company is cognizant of the need to make timely disclosure of material information. However, as set out above, the Company only intended to commence production and commercialization of the Biolidics Test Kits upon procurement of the product liability insurance. As such, the Board believes that the signing of the manufacturing agreement or the approval of the HSA would not be deemed material information unless there is certainty of commencement of production which is dependent on the procurement of a product liability insurance.

Question 5

Please elaborate on what a 'provisional' authorization entails and what are the further conditions/tests required to be performed. What would be the next steps that the Company will take and what other regulatory approvals are required.

Company's response: Based on the provisional authorization from HSA, the Company may export the product and market the product in Singapore, subject to the following terms:

- a. The "provisional authorisation" from HSA will be valid until HSA advises otherwise;
- b. Biolidics will need to comply with standard post-market duties and obligations (e.g. Serious adverse events and recall reporting), and maintaining distribution records; and
- c. Biolidics will also be required to also comply with the following additional conditions:

- i. Submit the results of the real-time stability studies for the test once complete;
- ii. Submit the results of additional clinical evaluation of the test, if available;
- iii. Report any incorrect or inaccurate test results from this test as and when they become aware of; and
- iv. Seek prior approval from HSA for any changes or updates to the intended use for the test including expansion of sample types.

Save for the above, no other regulatory approvals are required for the Company's Biolidics Test Kits in its current form and use.

Question 6

Please explain how "detection of 2019-nCoV IgG/IgM antibodies in human serum, plasma and whole blood" is the same as "detection of the Novel Coronavirus 2019".

Company's response: The IgM and IgG antibodies are produced by the human body in response to SARS-CoV-2 (i.e the virus which causes Covid-19) infection. As such, the detection of the presence of these antibodies is an indication that the individual has been infected by SARS-CoV-2. This was supported by validation study performed in China which provided empirical evidence that the test kits are specific to SARS-CoV-2.

Question 7

MOH's guidance on use of Serology Rapid Test Kits for Covid-19 Infection dated 3 Apr 2020 stated that *"Based on the currently available evidence, including local validation data, there is NO ROLE for COVID-19 serology (IgM/ IgG) rapid test kits in the clinical diagnosis of COVID-19 infections. Medical practitioners should not be using such serology rapid test kits in the evaluation of persons with symptoms of acute respiratory infection."*

In the provisional authorization page for Biolidics on HSA website, it was also stated that *"Biolidics2019-nCoV IgG/IgM Detection Kit is intended for the qualitative detection of 2019-nCoV IgG/IgM antibodies in human serum, plasma and whole blood. The results from this test is not to be used for confirmatory testing or as sole basis for diagnosis. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplemental testing (e.g. RT-PCR). The kit is not intended for finger prick testing."*

However, in the Company's announcement of 30 Mar 2020 it was stated that *"...to customise and manufacture the Company's rapid test kits for the detection of the Novel Coronavirus 2019 (the "COVID-19 Rapid Test Kits")."*

Further, in the Company's press release announcements of 30 Apr 2020 and 1 Apr 2020 on the approval for Biolidics' Rapid Test Kit for Covid-19 by HSA Singapore and the FDA of Philippines, it was stated that *"Using serum, plasma or whole blood samples, Biolidics' rapid test kit can detect COVID19 with an accuracy of more than 95% in 10 minutes."*

In view of the above, please explain if the above announcements of 30 Mar 2020 and 1 Apr 2020 were factual, clear and succinct pursuant to App7A on Corporate Disclosure Policy, as well as balanced and fair pursuant to PN 7A on Continuing Disclosure, and compliant with requirements of CR703.

Board and Sponsor to provide responses and justifications.

Company's response: The Company understands that the MOH's guidance on use of Serology Rapid Test Kits for Covid-19 Infection dated 3 Apr 2020 ("MOH Guidance"), was to clarify that COVID-19 serology (IgM/ IgG) tests should not be used as the sole basis for diagnosis of Covid-19 infections.

In the Company's announcement and subsequent press releases, it was stated that the Company's rapid test kits are "for the detection of the Novel Coronavirus 2019 (the "COVID-19 Rapid Test Kits)". The Company had been careful not to claim that its COVID-19 Rapid Test Kits are for "diagnosis" of Covid-19 infections, or making statements which may be misleading to shareholders or potential investors.

The Company's COVID-19 Rapid Test Kits detects Novel Coronavirus 2019 through the detection of 2019-nCoV IgG/IgM antibodies ("Covid-19 Antibodies") in human serum, plasma and whole blood. The IgM and IgG antibodies detected using the test kit are specific to SARS-CoV-2 (i.e the virus which causes Covid-19). This was supported by the validation study performed in China, and therefore can be considered as a surrogate marker for the detection of COVID-19. As such, the Company had stated that its COVID-19 Rapid Test Kits are able to detect the Novel Coronavirus 2019. This statement is also consistent with the HSA's provisional approval which stated that "Biolidics2019-nCoV IgG/IgM Detection Kit is intended for the qualitative detection of 2019-nCoV IgG/IgM antibodies in human serum, plasma and whole blood". In subsequent press releases, the Company had also clarified that "the results from the test is not to be used for confirmatory testing or as sole basis for diagnosis. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplementary testing".

The Company's claim that "using serum, plasma or whole blood samples, Biolidics' rapid test kit can detect COVID19 with an accuracy of more than 95% in 10 minutes" is based on validation data obtained in studies conducted in the People's Republic of China, involving 570 samples from 5 hospitals. The Company wishes to highlight that the statement indicates accuracy of detection and not diagnosis. Such data had been submitted to the HSA as part of its application for the provisional authorisation for its COVID-19 Rapid Test Kits.

The Company had supplied its COVID-19 Rapid Test Kits on the 3 April 2020, to conduct validation studies in conjunction with the National Public Health Laboratory/NCID. Additionally, the Company will begin a separate study with NUH commencing on 6 April 2020. The clinical validation to be performed at National Public Health Laboratory/NCID and NUH is to 1) verify the clinical performance claim in the product insert (i.e. sensitivity and specificity) using local patient samples; 2) evaluate the feasibility of using finger pricking instead of venepuncture sampling methodology to obtain whole blood samples.

In view of the above, the Board and the Sponsor believe that the Company's announcements and press releases of 30 Mar 2020 and 1 Apr 2020 were factual, clear and succinct, and the disclosures were balanced and fair and comply with the requirements of Rule 703 of the Catalist Rules.

Question 8

What is the financial impact of these developments on the Company?

Company's response: The Company is not able to ascertain the financial impact of these developments at the time of making the announcement as it has not received any firm orders for the test kits nor commenced manufacturing of the test kits.

Question 9

Why was the announcement made at 1710hrs, instead of after trading hours?

Company's response: The Company cleared the announcement on 30 March 2020 on or about 4.40pm and instructed the company secretary to release the announcement with the understanding that it would be done after trading hours. The Company believes that the company secretary may have released the announcement after 5pm as no specific instruction as to timing of the release of the announcement was given in this instance.

BY ORDER OF THE BOARD

Yee Pinh Jeremy
Non-Executive Non-Independent Chairman
9 April 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 Catalist. 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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