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**TBG Diagnostics Ltd**

# Quarterly Activities Report and Appendix 4C

- **The group earned total revenues of $1.3 mil during the quarter ($1.9 mil at 30 June 2020) and received cash flow boost incentive income of $50k**
- **TBG Biotechnology Corp. ("TBG Taiwan") received CE Mark approval of COVID-19 Nucleic Acid and Antibody Rapid Test Kits**
- **TBG Taiwan received US FDA Emergency Use Authorisation (EUA) for its COVID-19 nucleic acid test kits**
- **Applied for registration and certification for the Group's SARS-Cov-2 related diagnostic products in three (3 different countries)**

**Melbourne, Australia, 31 July 2020**: TBG Diagnostics Limited (ASX: TDL) ("TDL" or 'the Company"), releases today its Quarterly Activities Report and Appendix 4C for the quarter ended 30 June 2020.

## Principal activities

On 31 January 2020, the World Health Organisation (WHO) announced a global health emergency because of a new strain of coronavirus (COVID-19 outbreak) and the risks to the international community as the virus spreads globally beyond its point of origin. Because of the rapid increase in exposure globally, on 11 March 2020, the WHO classified the COVID-19 outbreak as a pandemic. The full impact of the COVID-19 outbreak continues to evolve at the date of this report. The Company has considered this as an opportunity and has taken significant steps to gain competitive advantage for the introduction of its Covid-19 products. The Group have obtained the following product certifications and approvals:

(i) ChangYe Medical Laboratory Corp (ChangYe) approved as a designated testing lab for coronavirus, ChangYe is a subsidiary of TBG Biotechnology Xiamen (TBG Xiamen). The Company has a 48.23% interest in TBG Xiamen.

(ii) CE Mark approval of TBG Xiamen's COVID-19 Virus Diagnostic Kit.

(iii) TBG Biotechnology Corp. ("TBG Taiwan") has received CE Mark approval of COVID-19 Nucleic Acid and Antibody Rapid Test Kits.

(iv) TBG Taiwan has received US FDA Emergency Use Authorisation (EUA) for its COVID-19 nucleic acid test kits.

(v) TBG Taiwan has received Taiwan Ministry of Health and Welfare Emergency Use Authorization (EUA) of the COVID-19 Nucleic Acid Test Kits

## Key highlights during the Quarter 30 June 2020

### Revenues and other income

The group delivered revenues of $1.3 mil during the quarter which doubled last quarter's revenues of $616k due mainly to increase in sales of high-resolution HLA-SBT products. Additionally, revenues from Covid-19 products amounting to $127k was also realised during the quarter. At 30 June 2020, total revenues amounted to $1.9 mil.

The parent company in Australia also received an income of $50k relating to cash flow boost incentive that are granted by the Australian government to eligible businesses during the economic downturn associated with COVID-19.

**TBG Taiwan received CE Mark approval of COVID-19 Nucleic Acid and Antibody Rapid Test Kits**

On 21 May 2020, the Group announced that its wholly owned subsidiary TBG Taiwan" has received the CE Mark approval for its ExProbe™ SARS-CoV-2 Testing Kit and SARS-CoV-2 IgG / IgM Rapid Test Kit.

CE Mark certification indicates that the ExProbe™ SARS-CoV-2 Testing Kit and SARS-CoV-2 IgG / IgM Rapid Test Kit meet the essential health, safety, and environmental protection requirements of the applicable European regulations to allow the sale of the kit throughout the European Economic Area as well as any country that accepts CE-mark, subject to satisfying regulatory requirements and obtaining import permits for individual countries. Both tests are manufactured by TBG Biotechnology Corp.in Taiwan and will be exported from Taiwan subject to meeting the regulatory requirements of the destination country. The ExProbe™ SARS-CoV-2 Testing Kit is a RNA based diagnostic kit that uses real time PCR technology with multiplex design to detect distinctive segments within RdRP, N and E genes of the SARS-CoV-2 virus in a single reaction. It is commonly used to confirm active infection of the SARS-CoV-2 virus. The SARS-CoV-2 IgG / IgM Rapid Test Kit test is a lateral flow assay that is able to detect IgG and IgM antibodies against specific protein epitopes on the N and S proteins of the SARS-CoV-2. The Company expects the test to take 15 minutes to complete and detect the presence of SARS-CoV-2 specific IgM and IgG antibodies in the blood, serum and plasma. IgM and IgG antibodies usually generated in the body 7-10 days after SARS-CoV-2 infection and can last for weeks. This test is often used to confirm if a person has been infected with the COVID-19 virus. This rapid test uses droplet of blood, serum or plasma as testing sample. Together, these two test products are expected to be able to confirm symptomatic individuals with an active SARS-CoV-2 viral infection and those who have been infected bySARS-CoV-2 and generated a specific antibody response.

**TBG Biotechnology Corp. ("TBG Taiwan") receives US FDA Emergency Use Authorisation (EUA) for its COVID-19 nucleic acid test kits**

On 12 June 2020, the Company's announced its wholly owned subsidiary TBG Taiwan has received an Emergency Use Authorisation(EUA) from the United States Food and Drug Administration (FDA) for its ExProbeTMSARS-CoV-2 Testing Kit.

The United States FDA has made the Testing Kit available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. Since the Testing Kit is made available under an EUA, it has not undergone the same type of review as an FDA-approved or cleared IVD.

The Testing Kit is one of 100 in vitro diagnostics test kits for detection and/or diagnosis of the novel coronavirus which have received FDA EUAs to date.

**Continued development and product registration of Covid-19 products**

The Group has been pro-actively engaged in the development, production, distribution, and sale of its SARS-Cov-2 related diagnostic products. The Group has applied for registration and certifications in three (3) different countries

**Listing Rule 4.7C.3**

In item 6 of the attached Appendix 4C of the cash flow report for the quarter, payments made to related parties pertain to the following:

- Director's fees to an Executive Chairman and two (2) Non-executive Directors of $40k;
- Management consultancy fees to a Non-executive director of $18k
- Payments to the group's investee company, TBG Biotechnology (Xiamen) for purchases of raw material inventories of $956k (TWD 19.3 mil); and production equipment of $136k (TWD 2.7 mil) relating to the production of Covid-19 test products

**About the Company**

TBG Diagnostics Limited is a company dedicated to the research and development, manufacturing, sales and marketing and services of Molecular Diagnostics (MDx) products, including test assays and instruments. With its research and development based in the US, Taiwan and China, TDL manufactures its products in its ISO13485 certified facilities in Xiamen, China serving the clinical labs of both hospitals and independent reference labs, blood centres and bone marrow registry labs around the world. TDL also operates an ASHI (the American Society for Histocompatibility and Immunogenetics) accredited HLA typing lab in Taipei, Taiwan serving bone marrow registries, cord blood banks and medical centres performing organ/bone marrow transplantations.

The Company's objective is to become one of the leading molecular diagnostics (MDx) companies in Asia and particularly in China.

Authorised by Jitto Arulampalam – Chairman

On behalf of the Board of Directors