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TBG Diagnostics Ltd

Quarterly Activities Report and Appendix 4C

- **The group earned total revenues of $900k during the quarter ($2.8 mil at 30 September 2020)**
- **TBG Biotechnology Corp. ("TBG Taiwan") Receives US FDA Emergency Use Authorisation (EUA) of the COVID-19 Antibody Rapid Test Kits**

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

(vi) TBG Taiwan has received US FDA Emergency Use Authorisation (EUA) of its COVID-19 Antibody Rapid Test Kits.

The group is also currently developing immune function related genetic marker, Killer cell Inhibitor Receptor (KRI) to assess and monitor the efficacy of adoptive Natural Killer (NK) using multiple diagnostic platforms including SSP, real-time PCR, SBT and NGS.

Key highlights during the Quarter 30 September 2020

Revenues and other income

The group delivered revenues of $900k (unaudited) during the quarter which mainly pertained to revenues from high-resolution HLA-SBT kits and testing services. At 30 September 2020, total revenues amounted to $2.8 million (unaudited) year to date.

TBG Taiwan Receives US FDA Emergency Use Authorisation (EUA) of the COVID-19 Antibody Rapid Test Kits

On 2 September 2020, the Company's wholly owned subsidiary, TBG Taiwan has received an Emergency Use Authorisation (EUA) from the United States Food and Drug Administration (FDA) for its TBG SARS-CoV-2IgG / IgM Rapid Test Kit.

The TBG SARS-CoV-2 IgG / IgM Rapid Test Kit is a lateral flow immunochromatography based diagnostic kit that uses colloidal gold technology to detect the presence of antibodies against N and S proteins of theSARS-CoV-2 virus in a test card. It is commonly used to confirm prior infection of the SARS-CoV-2 virus from serum and plasma samples. This test is manufactured by TBG Biotechnology Corp. in Taiwan and will be exported from Taiwan.

The United States FDA has made the Test 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 causesCOVID-19. Since the Test 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 41 in vitro diagnostics test kits for detecting antibodies against the novel coronavirus and one of 13 that uses the lateral flow immunochromatography rapid test platform that have received FDA EUAs to date.

TBG Taiwan has entered into Distribution Agreement with Medigen Biotechnology Corp. for the distribution of SARS-CoV-2 related diagnostic products globally (except Australia and New Zealand)

On 21 September 2020, the Company announced at the request of ASX that its wholly owned subsidiary, TBG Taiwan entered into a distribution agreement ("Distribution Agreement") with Medigen Biotechnology Corp. ("Medigen"), a major shareholder and parent company of TDL, on 15 February 2020, to distribute TBG Taiwan's SARS-CoV-2 related diagnostic products, including Rapid Test Kit (Colloidal Gold)and Nucleic Acid Test Kit (collectively, the "Test Kits").

The Distribution Agreement has expanded Medigen's existing exclusive distribution right granted under the distribution contract previously entered into between TBG Taiwan and Medigen in January 2015 to include the Test Kits. This provides an ability for expansion of the business of manufacturing and distributing the Test Kits through the distribution expertise and network of Medigen.

Medigen is the primary distributor for TBG Taiwan and has been distributing approximately 190 products for TBG Taiwan since 2015, and accordingly, the entry into the Distribution Agreement was undertaken in the ordinary course of TBG Taiwan's business. The key terms of the Distribution Agreement are as follows:

1. Medigen becomes the worldwide exclusive (except Australia and New Zealand) distributor of the Test Kits and TBG Taiwan is the manufacturer of the Test Kits to be distributed by Medigen.

2. Medigen is responsible for the registration, promotion, marketing and general customer service of the Test Kits and TBG Taiwan is responsible for the development and manufacturing of the Test Kits.

3. In consideration for the exclusive right to distribute the Test Kits, Medigen shall pay to TBG Taiwan an amount equal to 50%of the net profit generated by Medigen, in addition to the manufacturing costs, from each purchase order for the sales of the Test Kits. The "net profit" is defined in the Distribution Agreement as the sales price agreed between Medigen and its clients for each purchase order minus all manufacturing costs and marketing expenses of Medigen and TBG Taiwan (employee wages and related expenses are expressly excluded from the manufacturing and marketing expenses).

4. The term of the Distribution Agreement is 3 years commencing from 15 February 2020.

At 30 September 2020, revenues of $270,725 have been generated by TBG Taiwan from the sales of the Test Kits through Medigen under the Distribution Agreement. This revenue comprises the manufacturing cost payments, and the 50% net profit share payments, received from purchase orders for sales of the Test Kits.

The Company also notes that to expand sales and distribution of the Test Kits into the North and South American markets, TBG Taiwan and Medigen entered into a distribution agreement with Canadian

Securities Exchange–listed company Blackhawk Growth Group (CSE: BLR) and its local agent Boshic Advanced Materials Co., Ltd on 31 August 2020 ("Blackhawk Agreement"). The Blackhawk Agreement grants Blackhawk Growth Group the non-exclusive right to distribute the Test Kits in North and South America. The distribution right is exclusive for Canada, provided Canada Health Authority has approved the Test Kits and provided minimum order and sales levels are maintained by Blackhawk Growth Group.

ASX Suspension

The Company's shares have remained suspended from trading on ASX since March 2020. The Company has responded to all ASX queries and has requested that TDL shares resume trading. The Company has received no information from ASX in regard to the timing of the removal of suspension from trading. ASX has advised it will be issuing further queries and requests for information to TDL.

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 (3) Non-executive Directors of $50k;
- Management consultancy fees to a Non-executive director of $12k; and
- Payments to the group's investee company, TBG Xiamen, for purchases of inventory and consumables of $87k (TWD 1.8 mil).

Summary of operating expenditures during the quarter

Item	Category	Amount ($A'000)
(a)	research and development	(29)
(b)	product manufacturing and operating costs[1]	(1,807)
(c)	advertising and marketing	(61)
(d)	leased assets	(89)
(e)	staff costs	(332)
(f)	administration and corporate costs	(466)
	Total	**(2,784)**

[1] This pertain to purchases of inventories, consumables and related costs for production use and research and development processes.

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