

Appendix 4E

Preliminary Final Report

Name of Entity: TBG Diagnostics Limited

82 010 975 612

The directors present this preliminary report on the consolidated entity consisting of TBG Diagnostics (referred to as “TBG” or the “Company”) ABN 82 020 975 612 and the entities it controlled (referred to as the “Group”) during the year ended 31 December 2020.

1. Details of the reporting period

Current Period: 1 January 2020 – 31 December 2020

Previous Corresponding Period: 1 January 2019 – 31 December 2019

2. Results for announcement to the market

				<u>\$'000</u>
Revenue from continuing operations	Up	37.7%	to	\$4,606
Loss from ordinary activities after income tax attributable to members	Down	68.4%	to	(\$3,549)
Net profit attributable to members	Down	672.3%	to	(\$3,549)

Explanation of revenue

Of the total revenues, 55% pertained to revenues from HLA products which mainly include sequence based typing (SBT) and sequence specific primer (SSP) testing kits and services; while 29% pertained to revenues derived from Covid-19 testing kits consisting 84% of the total revenues.

Explanation of Net Profit after Tax

The net loss for the year ended 31 December 2020 was \$3,548,975 compared to a net profit of \$620,137 in prior year. The significant decrease is due to prior year's gain on discontinued operations relating to the disposal of the China group, TBG Biotechnology (Xiamen) Inc and its subsidiaries (“TBG Xiamen”). This is in spite of the impairment loss recognised associated to the same equity accounted investment.

Prior year's results also included income pertaining to the early settlement of the deferred consideration of PG500 assets that were sold in 2016.

Excluding discontinued operations and the associated impairment in prior year, decrease in net loss would have been \$784,363 from prior year.

3. Consolidated Statement of Profit and Loss and Other Comprehensive Income

Refer to page 15 and 16.

4. Consolidated Statement of Financial Position

Refer to page 17.

5. Consolidated Statement of Changes in Equity

Refer to page 18.

6. Consolidated Statement of Cash Flows

Refer to page 19.

7. Net tangible assets per ordinary share

	Current Period	Previous corresponding period
Net tangible asset backing per ordinary security (cents)	2.7	5.9

8. Dividends

No dividend for the year ended 31 December 2020 has been declared or paid to shareholders.

9. Dividend/distribution reinvestment plan

No dividend/distribution reinvestment plan for the year ended 31 December 2020.

10. Details of controlled entities

10.1 Name of entity (or group of entities) over which control was gained	N/A
10.2 Name of entity (or group of entities) over which control was lost	N/A
10.3 Date control was lost	N/A
10.4 The contribution of such entities to the reporting entity's profit	N/A

11. Details of associates and joint venture entities

11.1 Name of the entities	TBG Biotechnology (Xiamen) Inc. including: <ul style="list-style-type: none"> • XiaDe (Xiamen) Biotechnology Co, Ltd • TBG Biotechnology (HuNan) • Changsha TBG Digital Cloud • Changsha ChangYe Medical Laboratory Corp • Changsha ChangYe Medical Technology Ltd • Changsha ChangYe Medical Inspection Institute • Beijing ChangYe Medical Laboratory Ltd.
11.3 Group's aggregate share of associates and joint venture entities/ profit (loss) ¹ Group's aggregate share of associates and joint venture entities' net loss for the current period. ² Group's aggregate share of associates and joint venture entities' net loss for the prior period 1 May 2019 to 31 Dec 2019 Refer to note 12 for details.	Loss contribution: \$641,952 ¹ Previous corresponding period: \$2,347,328 ²

12. Auditing Status

This report is based on accounts which are in the process of being audited.

13. Other significant information

Refer to commentary on result below.

14. Audit disputes or qualifications

This report is based on accounts which are in the process of being audited.

15. Results and Review of Operations

Company Overview

The principal activities of TBG Diagnostics Limited during the period were focused on the research and development, manufacturing, sales and marketing and services of Molecular Diagnostics (MDx) products, including assays and instruments.

The Company's objective is to become one of the leading molecular diagnostics (MDx) companies in Asia and particularly in China. Due to its unparalleled performance in immune matching ability, molecular diagnostics is becoming an essential tool in helping the clinician with critical transplant decisions. TBG is continually pushing to the forefront of molecular testing for diagnostics. From the extraction of nucleic acids, amplification and detection of infectious diseases, genotyping and viral load testing, TBG is committed to expanding the applications of our core technology.

Operating and Financial Review

Operating Results for the Year

To be read in conjunction with the attached Financial Report.

The consolidated operating result for the period ended 31 December 2020 was a net loss of \$3,548,975, being a decrease of 672.3% over the 31 December 2019 net profit of \$620,137.

The significant decrease is due to prior year's gain on discontinued operations relating to the disposal of the China group, TBG Biotechnology (Xiamen) Inc and its subsidiaries ("TBG Xiamen"). This is in spite of the impairment loss recognised associated to the equity accounted investment.

Prior year's results also included income pertaining to the early settlement of the deferred consideration of PG500 assets that were sold in 2016.

Excluding discontinued operations and the associated impairment in prior year, decrease in net loss would have been \$784,363 from prior year.

The following table summarises the consolidated results:

		12 months ended	12 months ended
		31 Dec 2020	31 Dec 2019
	% Change	\$	\$
Revenue	37.7	4,605,983	3,345,592
Cost of Sales	136.9	(1,948,907)	(822,621)
Other income	267.3	590,858	160,863
Administrative and corporate expenses	54.0	(2,956,946)	(1,920,531)
Research and development expenses	17.3	(2,416,976)	(2,060,896)
Selling expenses	(18.0)	(564,846)	(688,417)
Share of net losses of associates	(72.7)	(641,952)	(2,347,328)
Impairment loss	(96.9)	(216,189)	(6,888,651)
Gain on discontinued operations	(100.0)	-	11,842,126
Net profit (loss)	(672.3)	(3,548,975)	620,137

15. Results and Review of Operations (cont'd)

Earnings/ (Loss) per Share and Net Tangible Assets per Share

		12 months ended	12 months ended
		31 Dec 2020	31 Dec 2019
	% Change	\$	\$
Basic and diluted loss per share	(672.3)	(1.6)	0.3
Net tangible assets per share*	(54.9)	2.7	5.9

* Includes right-of-use assets

Management Discussion and Analysis

Revenue and Other Income

Total revenues earned during the year increased 37.7% to \$4,605,983 in 31 December 2020 (2019: \$3,345,592) due to increase in sales revenues from existing customers. Additionally, sales from COVID-19 test kits also contributed to the positive result consisting 29% of total revenues. Related party sales to the parent, Medigen Biotechnology Corp. amounted to \$1,775,066 (2019: \$448,616). Related party sales to the group's investee company, TBG Xiamen, amounted to \$689,114 (2019: \$866,436). Total related party sales composed 53.5% (2019: 39.3%) of total revenues.

Other income increased 267.3% to \$590,858 (2019: \$160,863) mainly due to recovery of accounts previously impaired. During 2020, the parent entity also received 2,500,000 Zucero ordinary shares as described in note 1, with an attributed fair value at \$153,695. Furthermore, the parent company in Australia received an income of \$54,960 relating to cash flow boost incentive that are granted by the Australian government to eligible businesses during the economic downturn associated with COVID-19.

		12 months ended	12 months ended
		31 Dec 2020	31 Dec 2019
	% Change	\$	\$
Revenue and other income			
Sales revenue	41.6%	4,341,730	3,066,839
Technical services revenue	(5.2%)	264,253	278,753
Interest and other income	267.3%	590,858	160,863
Total revenue and other income	48.2%	5,196,841	3,506,455

Research and Development (R&D) Expenses

Research and development expenditure increased 17.3% to \$2,416,976 (2019: \$2,060,896) during the year ended 31 December 2020.

During the year, the group incurred product development and registration costs in relation to its COVID-19 diagnostics products as a pro-active response to the increasing need to prevent the spread of coronavirus which was described by the World Health Organisation (WHO) as global 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.

During the year, 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 Xiamen. The Company has a 48.23% interest in TBG Xiamen.
- (ii) CE Mark approval of TBG Xiamen's COVID-19 Virus Diagnostic Kit.

15. Results and Review of Operations (cont'd)

Research and Development (R&D) Expenses (cont'd)

- (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.
- (vi) TBG Taiwan has received US FDA Emergency Use Authorisation (EUA) of its COVID-19 Antibody Rapid Test Kits.
- (vii) TBG Xiamen has received CE Mark approval for its SARS-CoV-2 Antigen Rapid Test.

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

TBG is continuously focused on the development of molecular diagnostics in Immunogenetics. Based on multiplex Polymerase Chain Reaction (PCR) technology, the Group is also developing products for infectious disease diagnostics.

The primary activities of the R&D division pertains to the development of various detection kits for various diseases which are as follows:

Transplantation

Clinical studies have clearly shown that HLA gene matching between the donor and recipients of organs and stem cell transplants are key prognostic markers of the transplant success rate including immediate rejection as well as long term survival of the transplanted organ/cell. The applications of HLA genotyping not only includes the traditional donor matching against transplant recipients, but also to establish a global database of HLA typed donors from healthy blood donors or donated cord bloods, determine potential adverse drug reactions, and lastly, the diagnostic of specific autoimmune diseases. IVD products are currently provided for both LOW and HIGH resolutions.

Blood Safety

Once blood has been collected by the blood bank, every unit of blood must be screened for the presence of specific pathogenic microorganisms. While each blood centre across the globe has adopted different screening protocols, most of them will screen for Hepatitis B virus (HBV), Hepatitis C virus (HCV), and Human Immunodeficiency Virus (HIV).

Oncology

Molecular diagnostics in the field of oncology are now growing rapidly. Oncology tests can be used for many different indications, including screening to identify patients at risk of developing cancer, screening for early detection of cancer, determining prognosis, predicting response to therapy and monitoring patients both during and after treatment.

Infectious Disease

Molecular diagnostics for infectious diseases has been widely used and it is currently the largest application for molecular diagnostics. The driving force behind future infectious IVD testing market expansion will be the detection of hospital acquired infection, sexually transmitted diseases and human papilloma virus (HPV).

15. Results and Review of Operations (cont'd)

Research and Development (R&D) Expenses (cont'd)

Hereditary Genetics Testing

Genetic testing identifies specific inherited changes in a person's chromosomes, genes, or proteins. Genetic mutations can have harmful, beneficial, no effect, or cause uncertain effects on health. Genetic testing can confirm whether a condition is, indeed, the result of an inherited syndrome. Genetic testing is also performed to determine whether family members without obvious illness have inherited the same mutation as a family member who is known to carry a disease-associated mutation. We currently provide HLA B27 IVD products for Ankylosing Spondylitis as well as HLA-DQB IVD Products for Celiac and Narcolepsy.

A total solution

In order to provide a "sample to answer" workflow, TBG is also developing a fully integrated automation system based on Real Time PCR technology. Built upon this system, we aim to advance efficiency and accelerate results, ultimately improving the quality of products, reducing laboratory costs, and operator safety.

COVID-19 Pandemic

In December of 2019, a novel corona virus was first identified in Wuhan, China and later referred to as COVID-19. Within the first 3 months of 2020, COVID-19 has spread worldwide and caused a pandemic with over 1 million infected and 50,000 deaths. Without any vaccine or effective treatment, the only way to contain this pandemic is by viral screening and isolation. Countries that have successfully contained the virus have demonstrated that massive viral screening is the key to effective containment. The most common technology for massive viral screening is by RNA based real time PCR. In response, TBG had utilized its prior experience in viral IVD and produced RNA based testing kits against COVID-19. With TBG's supply chain in both China and Taiwan, TBG will be able to offer a stable supply of COVID-19 products globally.

Selling expenses

Selling expenses decreased 18% to \$564,846 (2019: \$688,417). During the year, promotional campaigns and related marketing travel plans were either put on hold or cancelled due to the impact of COVID-19.

Administrative and Corporate Expenses

Administrative and corporate expenses increased 54% to \$2,956,946 (2019: \$1,920,531) primarily due to increased audit, legal and management consultancy fees mainly incurred by the parent entity.

Gain / (Loss) on Discontinued Operations

There were no gains or losses on discontinued operations during the period.

In prior year, gain on discontinued operations of \$11,842,126 pertained to income of \$5,999,000 applicable to the full settlement of the deferred receivable relating to the PG500 assets that were sold in 2016. The prior year disposal of its subsidiary in China, TBG Xiamen, resulted to a gain of \$5,843,126.

Refer to *note 4* for further details.

Impairment loss

At 31 December 2020, impairment loss of \$216,189 (2019: \$6,888,651) was recognised in relation to certain receivables and investment. In 2019 prior year, impairment loss pertained to the equity accounted investment in TBG Xiamen and related receivables as the recoverable amounts were determined to be significantly lower than their carrying amounts.

15. Results and Review of Operations (cont'd)

Liquidity and Cash Resources

The Group ended the financial year with cash and cash equivalents totalling \$3,777,188 compared with \$5,205,131 at 31 December 2019. Cash of \$3,391,511 was disbursed during the year to fund consolidated net operating activities, compared to \$2,323,704 in 2019. Bulk of expenditures pertained to oncology costs relating to current products and products under new development of the research and development activities in Taiwan including Covid-19 testing kits.

During the year, the Company disbursed \$10,759,393 to fund its normal operations whilst collected \$7,334,731 from its trade customers. The parent company in Australia received an income of \$54,960 relating to cash flow boost incentive that are granted by the Australian government to eligible businesses during the economic downturn associated with COVID-19.

In prior year, the Company received a total of \$1.9 million from Zucero Therapeutics Ltd as the full and final settlement of the receivable from the sale of PG500 assets (note 4 (ii)).

Cash outflows from investing activities amounted to \$287,391 (2019: \$729,875), of which \$212,391 was used for the purchase of testing and machinery equipment in Taiwan and \$75,000 was used for the acquisition of investment (note 5).

In prior year, the Group had cash outflows of \$327,534 resulting from the disposal of its subsidiary in China, TBG Xiamen. Following its disposal, the Group invested an additional \$2.1 million (US\$ 1.430 million) via participation of rights issue resulting to a change of its shareholding in TBG Xiamen to 48.23%.

Cash outflows from financing activities amounted to \$2,091,718 (2019: \$767,545), of which \$205,946 pertained to payment of office leases.

During the year, the Group obtained total short-term bank loans of \$4,852,050 to finance its operational activities in Taiwan of which \$2,554,386 has been paid. At 31 December 2020, total short-term and long-term bank borrowings amounted to \$3,221,864. These short-term loans are payable within six (6) to twelve (12) months whilst long-term loan is payable within three (3) years. These borrowings were made to finance operational needs of the subsidiaries.

Cash and cash equivalents at 31 December 2020 were represented by a mix of highly liquid interest-bearing investments with maturities of up to 90 days and deposits on call.

Funding Requirements

The Group expects to incur substantial future expenditure in light of its research and development programs, manufacturing facility expansion and sales growth plans.

At present, TBG is undertaking to continue product development and the manufacture of its wide range of molecular diagnostics products and an integrated automated clinical system. Prior to full product launches, TBG needs to secure clinical trials and obtain regulatory approvals of its internally developed products and build its competitive advantage to achieve its growth plans. Significant cash requirements are required to achieve these objectives.

Future cash requirements will depend on a number of factors, including the scope and results of nonclinical studies and clinical trials, continued progress of research and development programs, the company's out-licensing activities, the ability to generate positive cash flow from the molecular diagnostics (MDx) business, the ability to generate revenues from the commercialisation of drug development efforts and the availability of other funding.

15. Results and Review of Operations (cont'd)

Funding Requirements (cont'd)

The Company estimates that the current cash and cash equivalents are sufficient to fund its on-going operations for at least 12 months from the date of this report. This excludes capital requirements outside of normal operating activities.

In light of the continuing merger and acquisition strategies, the Group is also looking further at various funding arrangements to finance any potential acquisition requirements, and to expand its cash reserves and capital resources.

Significant Changes in the State of Affairs

(a) Group's responses to the impact of coronavirus pandemic

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 is therefore uncertain as to the full impact that the pandemic will have on its financial condition, liquidity, and future results of operations during 2020.

However, the Group considered this situation as an opportunity and utilised its technology advantage and expertise in the production of RNA based testing kits against COVID-19. The Group has developed Nucleic Acid and Antibody Rapid Test Kits, ExProbe™ SARS-CoV-2 Testing Kit and SARS-CoV-2 IgG/IgM Rapid Test Kit, of which have received CE Mark, approvals and registrations in selected countries.

The following related events took place during year ended 31 December 2020.

(i) ChangYe approved as a designated testing lab for coronavirus

On 27 February 2020, the Group announced that Changsha ChangYe Medical Laboratory Corp. ('ChangYe'), a subsidiary of the Group's investee company TBG Xiamen, has been approved by the Health Competent Authority of the Province of Hunan (China) as a designated testing lab for 2019-nCov among other labs. As a designated lab, currently considerable samples from all over Hunan Province have been sent to ChangYe Medical Laboratories for analysis service, mainly from hospitals and corporate clients whose employees have to be screened.

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

On 18 March 2020, the Group's investee company TBG Xiamen, a China based molecular diagnostics company, has received the CE Mark approval for its COVID-19 Nucleic Acid Diagnostics Kit. CE Mark certification indicates that the COVID-19 Nucleic Acid Diagnostics Kit meets 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. This RNA based diagnostic kit uses real time PCR technology platform with 3 colour labelling to detect distinctive segments within RDRP, N and E genes of the SARS-CoV-2 virus.

Subsequently on 6 April 2020, the Group has been advised that the Chinese Government has now banned the export of all COVID-19 diagnostics kits that have not obtained the required China medical device product registration certification. TBG Xiamen's COVID-19 Virus Diagnostic Kits do not currently have China medical device product registration certification required under the new export requirements as recently announced by the Chinese Government, therefore TBG Xiamen is currently unable to sell and export their COVID-19 Nucleic Acid Diagnostics Kits from China. Without the China medical device product registration certification, TBG Xiamen is also currently unable to sell their COVID-19 Nucleic Acid Diagnostics Kits within China. While TBG Xiamen has received interest from several buyers, in light of these new restrictions no COVID-19 Nucleic Acid Diagnostics Kits will be exported or sold while these restrictions remain in place or until TBG Xiamen receives the required certifications for sale and export. TBG Xiamen intends to apply for the relevant regulatory approvals to allow for the sale and distribution of the COVID-19 Nucleic Acid Diagnostics Kits to regions within Europe and Asia as well as the USA.

15. Results and Review of Operations (cont'd)

Significant Changes in the State of Affairs (cont'd)

(a) Group's responses to the impact of coronavirus pandemic (cont'd)

On 5 May 2020, the Group further received notification from TBG Xiamen that the Chinese Department of Commerce has lifted these bans restricting the exportation of TBG Xiamen's CE Marked COVID-19 Nucleic Acid Test Kits. Following the lift of the export ban the COVID-19 Nucleic Acid Test Kits are now able to be exported from China for sale throughout the European Economic Area subject to individual countries accepting import of the test kits.

(iii) TBG Biotechnology Corp. ('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 Biotechnology Corp. ("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 by SARS-CoV-2 and generated a specific antibody response.

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

On 12 June 2020, TBG Taiwan has received an Emergency Use Authorisation (EUA) from the United States Food and Drug Administration (FDA) for its ExProbe™ SARS-CoV-2 Testing Kit. 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 from a specified range of upper and lower respiratory samples. This test is manufactured by TBG Biotechnology Corp. in Taiwan and will be exported from Taiwan.

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 EUA for the Testing Kit is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

Under the EUA, the ExProbe SARS-CoV-2 Testing Kit is only authorised for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

15. Results and Review of Operations (cont'd)

Significant Changes in the State of Affairs (cont'd)

(a) Group's responses to the impact of coronavirus pandemic (cont'd)

The FDA concluded that the Testing Kit met the criteria for issuance of the EUA which are listed in Section I on page 2 of the Letter of Authorisation. A full copy of the Letter of Authorisation from the FDA, which includes the conditions attached to the EUA, is available on the FDA website at <https://www.fda.gov/media/138819/download>.

The Fact Sheets for Healthcare Providers and Patients for the Testing Kit and the Instructions for Use are also available from the FDA website at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#COVID19ivd>.

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.

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

On 29 July 2020, TBG Taiwan received an Emergency Use Authorisation (EUA) from the Taiwan Ministry of Health and Welfare ("MOHW") for its ExProbe™ SARS-CoV-2 Testing Kit. The ExProbe™ SARS-CoV-2 Testing Kit ("Testing Kit") is an 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 from a specified range of upper and lower respiratory samples. This test is manufactured by TBG Biotechnology Corp. in Taiwan. The Taiwan MOHW has made the Testing Kit available under an emergency access mechanism called an EUA. The EUA is supported by the Taiwan MOHW 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 EUA for the Testing Kit is in effect from 24 July 2020 until 31 December 2021.

The Testing Kit is one of 10 in vitro diagnostics nucleic acid test kits for detection and/or diagnosis of the novel coronavirus which have received Taiwan EUAs to date.

(vi) 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-2 IgG / 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 the SARS-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 causes COVID-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.

15. Results and Review of Operations (cont'd)

Significant Changes in the State of Affairs (cont'd)

(a) Group's responses to the impact of coronavirus pandemic (cont'd)

(vii) *TBG Xiamen received CE Mark approval for its SARS-CoV-2 Antigen Rapid Test*

On 30 October 2020, CE Mark approval was granted to TBG Xiamen and confirmation of this approval was subsequently received on 10 November 2020.

CE-Mark certification indicates that the SARS-CoV-2 Antigen Rapid Test meets the essential requirements of all the applicable European regulations and allows for its sale throughout the European Economic Area as well as any country that accepts CE-mark, subject to satisfying regulatory requirements and obtaining import permits for individuals countries. This antigen rapid test kit is manufactured by TBG Xiamen in China and will be exported from China.

SARS-CoV-2 Antigen Rapid Test is a lateral flow assay that is able to detect the presence of SARS-CoV-2 (COVID-19) virus in human throat swab and nasal swab samples.

The Group has been continuously producing and progressing its COVID-19 products towards approvals and registration in various countries to expand market where TBG's diagnostics products are recognised.

These measures are considered by the Group to mitigate any potential financial impact associated with business risks resulting from the coronavirus pandemic.

(b) 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.

15. Results and Review of Operations (cont'd)

Significant Changes in the State of Affairs (cont'd)

At 31 December 2020, revenues of \$1,332,961 have been generated by TBG Taiwan from the sales of the SARS-CoV-2 related 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.

(c) Investment in Zucero Therapeutics Limited ("Zucero")

On 3 May 2019, the Company announced that it has entered into a Deed of Settlement with Zucero for the full settlement of the \$5,999,000 deferred consideration payable by Zucero following the purchase of shares in the capital of Progen PG500 Series Pty Ltd from the Company under the Share Sale Agreement executed on 22 August 2016. Pursuant to the Deed of Settlement, the Company received \$1,999,000 cash and 10,000,000 preference shares in Zucero at an issue price of \$0.40 per share with a total value of \$4,000,000 as full settlement of the deferred consideration. Following the issuance of the preference shares, the Company holds 7.89% in the capital of Zucero.

On 30 November 2020, the Company and Zucero executed a Deed of Conversion Notice whereby the Company agreed that the Company's preference shares in Zucero will be converted to ordinary shares pursuant to the Preference Share Terms set out in the Deed of Settlement entered into by the Company on 1 May 2019, subject to Zucero satisfying a number of conditions with regards to Zucero's intended listing on the ASX in the first half of calendar year 2021 (including in particular Zucero being granted conditional approval to list on ASX).

Contemporaneously with the entry into the Deed of Conversion Notice, the Company, Zucero, Seabreeze Fire Pty Ltd ("Seabreeze") and Christopher Burrell also entered into a deed pursuant to which there were mutual releases and under which, in consideration of the Company entering into the Deed of Conversion Notice, Seabreeze agreed to transfer to the Company 2,500,000 fully paid ordinary shares in Zucero (in addition to the Preference Shares).

On 31 December 2020, the Company holds 10,000,000 preference shares and 2,500,000 ordinary shares in Zucero representing 9.6% in the issued share capital of Zucero.

(d) Australian Stock Exchange (ASX) Suspension

The Company's shares have remained suspended from trading on Australian Stock Exchange (ASX) since March 2020. ASX has issued further queries and requests for information to the Group to which the Group is responding to.

Significant Event after the Reporting Date

Establishment of wholly-owned subsidiary TDL Holding Co.

On 4 February 2021, the Group established a new wholly owned offshore subsidiary, TDL Holding Co., in Cayman Islands ("TDLH") under TBG Diagnostics Limited. Under the new structure, the Company's wholly owned subsidiary in Cayman Islands, TBG Inc, ("TBG Cayman") will transfer 100% of the net assets of TBG Taiwan and TBG Texas to TDLH who will then hold 100% of the equity capital of TBG Taiwan and TBG Texas. TBG Inc will continue to hold 48.23% of the equity capital of TBG Xiamen, the group's investee company in China.

Significant Event after the Reporting Date (cont'd)

After the proposed group restructure, the equity interests of the group in the subsidiaries and associates will remain unchanged. The group still holds 100% of the equity capital of TBG Taiwan and TBG Texas and 48.23% of the equity capital of TBG Xiamen.

The purpose of the proposed group restructure is to allow TBG Inc to have freedom to serve as listing entity for Initial Public Offering (IPO) on international stock exchanges, facilitating fundraising of the group.

16. Outlook and Prospects for 2021

The likely developments in the year ahead include:

- (i) Further development of new product, Natural Killer (NK) Cell Profile Gene Panel on multiple diagnostic platforms;
- (ii) Further development of HLA NGS products and related software and progress towards product registration;
- (iii) Further develop, promote and sell the Group's tailored Covid-19 Nucleic Acid and Antibody Rapid Test Kits in licensed territories, as one of the main product pipelines addressing the global need of testing kits that will potentially contribute against the spread of coronavirus pandemic;
- (iv) Continue to look for opportunities for expansion of the Group's core technology through merger and acquisition;
- (v) On-going provision of necessary assistance to associates in China in promoting TBG products; and
- (vi) Conduct a capital raising to ensure adequate resources are available to achieve growth objectives, product development and increase assets portfolio.

Consolidated Statement of Profit and Loss
For the Year Ended 31 December 2020

		Consolidated	
	Note	12 months ended 31 Dec 2020 \$	12 months ended 31 Dec 2019 \$
REVENUE FROM CONTINUING OPERATIONS	3 (a)	4,605,983	3,345,592
Cost of Sales		<u>1,948,907</u>	822,621
GROSS PROFIT		<u>2,657,076</u>	2,522,971
Other income	3 (b)	590,858	160,863
EXPENSES			
Research and development expenses		(2,416,976)	(2,060,896)
Administrative and corporate expenses		(2,956,946)	(1,920,531)
Selling expenses		(564,846)	(688,417)
Impairment loss	3 (g)	<u>(216,189)</u>	(6,888,651)
		<u>(6,154,957)</u>	(11,558,495)
Loss before income tax		(2,907,023)	(8,874,661)
Share of net loss of associates accounted for under the equity method	12	<u>(641,952)</u>	(2,347,328)
LOSS FROM CONTINUING OPERATIONS BEFORE TAX		(3,548,975)	(11,221,989)
Income tax expense		<u>-</u>	-
LOSS FROM CONTINUING OPERATIONS		(3,548,975)	(11,221,989)
Gain from discontinued operations	4	<u>-</u>	11,842,126
NET PROFIT (LOSS) FOR THE YEAR		<u>(3,548,975)</u>	620,137

Consolidated Statement of Other Comprehensive Income
For the Year Ended 31 December 2020

		Consolidated	
	Note	12 months ended 31 Dec 2020 \$	12 months ended 31 Dec 2019 \$
NET PROFIT (LOSS) FOR THE YEAR		(3,548,975)	620,137
OTHER COMPREHENSIVE INCOME			
<i>Items that may be reclassified to profit or loss</i>			
Fair value loss on financial asset at fair value through other comprehensive income – initial recognition	5	(3,101,453)	-
Foreign currency translation		(415,904)	712,812
TOTAL OTHER COMPREHENSIVE INCOME (LOSS)		(3,517,357)	712,812
TOTAL COMPREHENSIVE INCOME (LOSS)		(7,066,332)	1,332,949
Net loss attributable to:			
- Equity holders of the Company	9	(3,548,975)	764,939
- Non-controlling interest		-	(144,802)
Total comprehensive income attributable to:			
- Equity holders of the Company		(3,548,975)	1,471,280
- Non-controlling interest		-	(138,330)
Total comprehensive income for the year attributable to owners of TBG Diagnostics Limited arises from			
- Continuing operations		(3,548,975)	(10,380,482)
- Discontinued operations		-	11,851,762
Basic and diluted loss per share – continuing operations attributable to equity holders of the Company (cents per share)	9	(1.6)	(5.2)
Basic and diluted loss per share (cents per share)	9	(1.6)	0.3

Consolidated Statement of Financial Position
As At 31 December 2020

	Note	Consolidated 31 Dec 2020 \$	31 Dec 2019 \$
ASSETS			
Current Assets			
Cash and cash equivalents	11	3,777,188	5,205,131
Trade and other receivables		773,598	227,332
Inventories		5,035,408	848,180
Prepayment and other current assets		261,875	127,264
Total Current Assets		9,848,069	6,407,907
Non-current Assets			
Other non-current assets		284,081	206,329
Plant and equipment	6	671,116	1,094,241
Right-of-use assets		1,090,123	187,697
Financial asset at fair value through other comprehensive income	5	1,052,242	4,000,000
Investment in associates accounted for under the equity method	12	1,939,022	3,143,236
Total Non-current Assets		5,036,584	8,631,503
TOTAL ASSETS		14,884,653	15,039,410
LIABILITIES			
Current Liabilities			
Trade and other payables		4,712,924	990,190
Borrowings	7	2,772,600	952,140
Provisions		62,276	49,922
Lease liabilities		195,057	190,798
		7,742,857	2,183,050
Non-current Liabilities			
Long term borrowings	7	449,264	-
Lease liabilities – non-current		895,255	-
Total Non-current Liabilities		1,344,519	-
TOTAL LIABILITIES		9,087,376	2,183,050
NET ASSETS		5,797,277	12,856,360
EQUITY			
Contributed equity	8	36,211,120	36,211,120
Reserves		572,092	4,264,334
Accumulated losses		(30,985,935)	(27,619,094)
TOTAL EQUITY		5,797,277	12,856,360

Consolidated Statement of Changes in Equity
For the Year Ended 31 December 2020

	Attributable to owners of TBG Diagnostics Limited							
	Contributed Equity	Accumulated losses	Fair value gains (losses) on financial asset at FVTOCI	Other reserves	Foreign currency translation reserve	Total	Non-controlling interests	Total equity
Consolidated	\$	\$	\$	\$	\$	\$	\$	\$
At 1 January 2019	36,211,120	(28,479,908)	-	321,740	3,221,853	11,274,805	574,337	11,849,142
Loss for the year	-	764,939	-	-	-	764,939	(144,802)	620,137
Other Comprehensive Income, net of tax	-	-	-	-	706,340	706,340	6,472	712,812
Total Comprehensive Income for the year	-	764,939	-	-	706,340	1,471,279	(138,330)	1,332,949
Transactions with owners in their capacity as owners:			-					
Expired options	-	95,875	-	(95,875)	-	-	-	-
Cost of share-based payments	-	-	-	110,276	-	110,276	-	110,276
Disposal of subsidiary	-	-	-	-	-	-	(436,007)	(436,007)
At 31 December 2019	36,211,120	(27,619,094)	-	336,141	3,928,193	12,856,360	-	12,856,360
At 1 January 2020	36,211,120	(27,619,094)	-	336,141	3,928,193	12,856,360	-	12,856,360
Loss for the year	-	(3,548,975)	-	-	-	(3,548,975)	-	(3,548,975)
Other Comprehensive Income, net of tax	-	-	(3,101,453)	-	(415,904)	(3,517,357)	-	(3,517,357)
Total Comprehensive Income for the year	-	(3,548,975)	(3,101,453)	-	(415,904)	(7,066,332)	-	(7,066,332)
Transactions with owners in their capacity as owners:								
Expired options	-	182,134	-	(182,134)	-	-	-	-
Cost of share-based payments	-	-	-	7,249	-	7,249	-	7,249
At 31 December 2020	36,211,120	(30,985,935)	(3,101,453)	161,256	3,512,289	5,797,277	-	5,797,277

Consolidated Statement of Cash Flows
For the Year Ended 31 December 2020

	Note	Consolidated 12 months ended 31 Dec 2020 \$	12 months ended 31 Dec 2019 \$
CASH FLOWS FROM OPERATING ACTIVITIES			
Receipts from customers		7,334,731	2,713,335
Payments to suppliers, employees and others		(10,759,393)	(5,122,848)
Government grants received		54,960	-
Interest received		31,154	106,804
Finance costs		(52,963)	(20,995)
NET CASH OUTFLOW FROM OPERATING ACTIVITIES		(3,391,511)	(2,323,704)
CASH FLOWS FROM INVESTING ACTIVITIES			
Payments for property, plant and equipment	6	(130,202)	(271,157)
Payments of development costs		(82,189)	-
Payments for acquisition of investment	5	(75,000)	-
Net cash inflow from settlement of deferred receivables		-	1,999,000
Payments for sale of TBG Xiamen		-	(327,534)
Payment for additional investment through exercise of rights issue in TBG Xiamen		-	(2,130,184)
NET CASH OUTFLOW FROM INVESTING ACTIVITIES		(287,391)	(729,875)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from bank borrowings		4,852,050	952,140
Repayment of bank borrowings		(2,554,386)	-
Principal elements of lease payments		(205,946)	(184,595)
NET CASH INFLOW FROM FINANCING ACTIVITIES		2,091,718	767,545
NET (DECREASE) IN CASH HELD		(1,587,184)	(2,286,034)
Net foreign exchange differences		159,241	756,374
Cash and cash equivalents at beginning of period		5,205,131	6,734,791
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	11	3,777,188	5,205,131

Notes to the financial statements

NOTE 1 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of preparation

This preliminary report is for TBG Diagnostics Limited (the 'Company') and its subsidiaries (the 'Group') for the year ended 31 December 2020. TBG Diagnostics Limited is a company limited by shares incorporated and domiciled in Australia whose shares are publicly traded on the Australian Securities Exchange (ASX) and the United States OTCQB Market.

The nature of the operations and principal activities of the Group are described in Note 2.

The preliminary report has been prepared on an accrual basis and is based on historical costs modified, where appropriate, by the revaluation of selected non-current assets, financial assets and financial liabilities for which the fair value basis of accounting has been applied.

The preliminary report does not include all the notes of the type normally included in annual financial statements. Accordingly, this preliminary report should be read in conjunction with the annual financial statements for the year ended 31 December 2019 and any public announcements made by TBG Diagnostics Limited during the year in accordance with the continuous disclosure requirements of the Australian Securities Exchange and the Corporations Act 2001.

Going Concern

The Group incurred consolidated net loss of \$3,548,975 for the year ended 31 December 2020. As at 31 December 2020, the Group has cash reserves of \$3,777,188, net current assets of \$2,105,212 and net assets of \$5,797,277.

Management contemplates a capital raising or other financing may be required to continue to fund operations in the future.

On 31 January 2020, the World Health organisation (WHO) announced a global health emergency because of a new strain of coronavirus (COVID-19) and the risks to the international community as the virus spreads globally. Because of the rapid increase in exposure globally, the WHO classified the COVID-19 outbreak as a pandemic. These events are having a significant negative impact on world stock markets, currencies and general business activities which could negatively impact the Group in a material adverse manner.

The ability of the Group to continue as a going concern is principally dependent upon one or more of the following:

- The ability of the Group to meet its revenue and cash flow forecasts;
- the ability of the Group to raise additional capital funding in the form of equity and/or government sponsored research;
- the continued support of the current shareholders.

These conditions give rise to material uncertainty which may cast significant doubt over the Group's ability to continue as a going concern.

In the past, the Group has been able to raise funds in order to meet its capital requirements and the directors will continue to explore ways to obtain the needed funding for the continuity and further development of the Group's assets.

The directors believe that the going concern basis of preparation is appropriate due to the following reasons:

- Management is closely monitoring its cash flow requirements against budget and expects to meet the current forecasts;

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Going Concern (cont'd)

- On 18 March 2020, the Group also announced that TBG Xiamen has received the CE Mark approval for its COVID-19 Nucleic Acid Diagnostics Kit. On 21 May 2020, the Group announced that TBG Taiwan also received the CE Mark approval for its COVID-19 Nucleic Acid Diagnostics Kit and Antibody Rapid Test Kits. Additionally, TBG Taiwan received US FDA Emergency Use Authorisation (EUA) of its COVID-19 Nucleic Acid Diagnostics Kits on 12 June 2020. Subsequently on 29 July 2020, TBG Taiwan also received Taiwan Ministry of Health and Welfare Emergency Use Authorisation of its COVID-19 Nucleic Acid Diagnostics Kits. Further on 2 September, TBG Taiwan has received US FDA Emergency Use Authorisation (EUA) of its COVID-19 Antibody Rapid Test Kits. On 10 November 2020, TBG Xiamen has received CE Mark approval for its SARS-CoV-2 Antigen Rapid Test. The Group expects to generate positive cash flows from sales of these diagnostics kits;
- To date the Group has funded its activities through issuance of equity securities where required and it is expected that the Group will be able to fund its future activities through further issuances of equity securities; and
- The directors believe there is sufficient cash available for the Group to continue operating until it can raise sufficient further capital to fund its ongoing activities.

Should the Group be unable to continue as a going concern, it may be required to realise its assets and extinguish its liabilities other than in the ordinary course of business, and at amounts that differ from those stated in the financial statements.

This financial report does not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts or classification of liabilities and appropriate disclosures that may be necessary should the Group be unable to continue as a going concern.

The accounting policies and methods of computation applied in this interim financial report are consistent with those applied in the previous financial year and the corresponding interim reporting period. The Company has adopted all of the new and revised Standards and Interpretations issued by the Australian Accounting Standards Board that are relevant to its operations and effective for the current reporting period.

Statement of compliance

The consolidated financial statements of the Group also comply with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

Summary of Significant Accounting Policies

Historical cost convention

The financial statements have been prepared on an accruals basis and are based on historical costs, modified, where applicable, by the measurement at fair value of selected non-current assets, financial assets and financial liabilities.

New, revised or amending Accounting Standards and Interpretations adopted

None of the new standards and amendments to standards that are mandatory for the first time for the financial year beginning 1 January 2020 affected any of the amounts recognised in the current period or any prior period and are not likely to affect future periods.

Basis of consolidation

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Basis of consolidation (cont'd)

Intercompany transactions, balances and unrealised gains on transactions between Group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Non-controlling interests in the results and equity of subsidiaries are shown separately in the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of financial position respectively.

Investments in subsidiaries held by the Group are accounted for at cost in the separate financial statements of the parent entity.

Business combinations and asset acquisitions

The acquisition method of accounting is used to account for all business combinations regardless of whether equity instruments or other assets are acquired. Cost is measured as the fair value of the assets given, shares issued or liabilities incurred or assumed at the date of exchange. Where equity instruments are issued in a business combination, the fair value of the instruments is their published market price as at the date of exchange. Transaction costs arising on the issue of equity instruments are recognised directly in equity.

All identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. The excess of the cost of the business combination over the net fair value of the Group's share of the identifiable net assets acquired is recognised as goodwill. If the cost of acquisition is less than the Group's share of the net fair value of the identifiable net assets of the subsidiary, the difference is recognised as a gain in the statement of profit or loss and other comprehensive income, but only after a reassessment of the identification and measurement of the net assets acquired.

Acquisitions of entities that do not meet the definition of a business contained in AASB 3 *Business Combinations* (IFRS 3) are not accounted for as business combinations. In such cases the Group identifies and recognises the individual identifiable assets acquired (including those assets that meet the definition of, and recognition criteria for, intangible assets in AASB 138 *Intangible Assets* (IAS 38) and liabilities assumed. The cost of the group of net assets is then allocated to the individual identifiable assets and liabilities on the basis of their relative fair values at the date of purchase. Such a transaction or event does not give rise to goodwill.

Investment in Associates

Associates are all entities over which the group has significant influence but not control or joint control. This is generally the case where the group holds between 20% and 50% of the voting rights. Investments in associates are accounted for using the equity method of accounting after initially being recognised at cost.

Under the equity method of accounting, the investments are initially recognised at cost and adjusted thereafter to recognise the group's share of the post-acquisition profits or losses of the investee in profit or loss, and the group's share of movements in other comprehensive income of the investee in other comprehensive income. Dividends received or receivable from associates and joint ventures are recognised as a reduction in the carrying amount of the investment.

When the group's share of losses in an equity-accounted investment equals or exceeds its interest in the entity, including any other unsecured long-term receivables, the group does not recognise further losses, unless it has incurred obligations or made payments on behalf of the other entity.

Unrealised gains on transactions between the group and its associates and joint ventures are eliminated to the extent of the group's interest in these entities. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred. Accounting policies of equity accounted investees have been changed where necessary to ensure consistency with the policies adopted by the group.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Fair Values

The fair values of TBG's financial assets and liabilities approximate their carrying value. No financial assets or liabilities are readily traded on organised markets in standardised form.

Significant accounting judgements, estimates and assumptions

The preparation of financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The carrying amounts of certain assets and liabilities are often determined based on estimates and assumptions of future events. The key estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of certain assets and liabilities are:

AASB 9 Financial Instruments

Fair value loss on financial assets measured at FVTOCI

As detailed in *note 5*, the Group has elected to recognise its investment in Zucero Therapeutics Ltd at fair value through other comprehensive income (FVTOCI). In determining the fair market value of the Group's investment in Zucero Therapeutics Ltd at FVTOCI, the Group adopted the Available Prices Methodology as the method consistently adopted from initial recognition of the financial asset based on readily observable capital raising transactions.

The estimated fair value loss pertaining to the Group's financial asset measured at FVTOCI was determined based on the most recent capital raising transaction of Zucero Therapeutics Ltd in June 2020, which resulted to a fair value loss on financial asset at FVTOCI of \$3,101,453 in the statement of other comprehensive income applicable to the 10,000,000 preference shares.

On 9 December 2020, an off-market share transfer of 2,500,000 ordinary shares in Zucero was made by Seebreeze to TBG in accordance with a deed dated 30 November 2020. These 2,500,000 ordinary shares have been determined to have an implied fair value of \$153,695 that resulted to a total fair value of the financial assets to \$1,052,242. The corresponding increase in the fair value by \$153,695 has been recognised as income in the Statement of Profit & Loss.

The Group considered the fair value of its investment in Zucero Therapeutics Ltd as at 31 December 2020 was implied by the aggregate fair value of the financial instruments issued under this recent capital raising completed by Zucero Therapeutics Ltd in June 2020. In determining the fair value of the financial instruments of this nature, the key required inputs were as follows:

- The discount rate adopted in the bond formula (which is generally higher than the rate of interest payable on the bond) applicable to the convertible note;
- The volatility adopted in the Black Scholes formula (which is generally determined with reference to the volatility of comparable companies) applicable to the embedded derivative and options; and
- The share price adopted in the Black Scholes formula applicable to the embedded derivative and options.

It is noted that the inputs required for a fair value assessment involved significant estimates and assumptions and required a high degree of judgements and complexities, having regard to the terms of the recent capital raising completed by Zucero Therapeutics Ltd in June 2020 and other information available to the Group (*see Note 5*).

The Group assessed these methods as the most appropriate methodology under the existing circumstances at 31 December 2020.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

AASB 15 Revenue from Contracts from Customers

(i) Sale of goods

The Group manufactures and sells molecular diagnostics. Sales are recognised when control of the products has transferred, being when the products are delivered to the customer, the customer has full discretion over the channel and price to sell the products, and there is no unfulfilled obligation that could affect the wholesaler's acceptance of the products. Delivery occurs when the products have been shipped to the specific location, the risks of obsolescence and loss have been transferred to the customer, and either the customer has accepted the products in accordance with the sales contract, the acceptance provisions have lapsed, or the group has objective evidence that all criteria for acceptance have been satisfied.

The molecular diagnostics products are sometimes sold with retrospective volume discounts based on aggregate sales over a fixed period. Revenue from these sales is recognised based on the price specified in the contract, net of the estimated volume discounts. Accumulated experience is used to estimate and provide for the discounts, using the expected value method, and revenue is only recognised to the extent that it is highly probable that a significant reversal will not occur. A refund liability (included in trade and other payables) is recognised for expected volume discounts payable to customers in relation to sales made until the end of the reporting period. No element of financing is deemed present as the sales are made with a credit term of 30 days, which is consistent with market practice. The group's obligation to provide a refund for faulty products under the standard warranty terms is recognised as a provision.

A receivable is recognised when the goods are delivered as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

(ii) Technical service revenue

The Group provides technical services of HLA (Human Leukocyte Antigen) typing. Revenue from providing services is recognised in the accounting period in which the services are rendered. For fixed-price contracts, revenue is recognised based on the actual service provided to the end of the reporting period as a proportion of the total services to be provided. This is determined based on the actual labour hours spent relative to the total expected labour hours.

Estimates of revenues, costs or extent of progress toward completion are revised if circumstances change. Any resulting increases or decreases in estimated revenues or costs are reflected in profit or loss in the period in which the circumstances that give rise to the revision become known by management.

(iii) Interest income

Revenue is recognised as interest accrues using the effective interest method. This is a method of calculating the amortised cost of a financial asset and allocating the interest income over the relevant period using the effective interest rate, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

(iv) Financing components

The group does not expect to have any contracts where the period between the transfer of the promised goods or services to the customer and payment by the customer exceeds one year. As a consequence, the group does not adjust any of the transaction prices for the time value of money.

(v) Government grants

Government grants are recognised as revenue when there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When grants are received prior to being earned, they are recognised as a liability in the statement of financial position.

When the grant relates to an expense item, it is recognised as income over the periods necessary to match the grant on a systematic basis to the costs that it is intended to compensate. Where the costs that correspond to the income received are prior year costs, the grant received is immediately recognised in the profit or loss.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

AASB 15 Revenue from Contracts from Customers (cont'd)

When the grant relates to an asset, the fair value is credited to a deferred income account and is released to the profit or loss and other comprehensive income over the expected useful life of the relevant asset by equal annual instalments.

Leases

The determination of whether an arrangement is or contains a lease is based on the substance of the arrangement and requires an assessment of whether the fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset.

Operating lease payments are recognised as an expense in the profit or loss on a straight-line basis over the lease term. Lease incentives are recognised in the profit or loss as an integral part of the total lease expense. There are no finance leases.

Cash and cash equivalents

Cash and short-term deposits in the statement of financial position comprise cash at bank and in hand and short term deposits with an original maturity of three months or less. For the purposes of the statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above.

Trade and other receivables

Trade receivables, which generally have 30-90 day terms, are recognised and carried at original invoice amount less an allowance for any uncollectible amounts

Trade receivables and contract assets

The group applies the AASB 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables and contract assets.

To measure the expected credit losses, trade receivables and contract assets have been grouped based on shared credit risk characteristics and the days past due. The contract assets relate to unbilled work in progress and have substantially the same risk characteristics as the trade receivables for the same types of contracts. The group has therefore concluded that the expected loss rates for trade receivables are a reasonable approximation of the loss rates for the contract assets.

Trade receivables and contract assets are written off when there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the group, and a failure to make contractual payments for a period of greater than 120 days past due.

AASB 9 Financial Instruments

(i) Investments and other financial assets

Classification

The group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through OCI, or through profit or loss); and
- those to be measured at amortised cost.

The classification depends on the entity's business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, this will depend on whether the group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income (FVOCI).

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

AASB 9 Financial Instruments (cont'd)

The group reclassifies debt investments when and only when its business model for managing those assets changes.

Measurement

At initial recognition, the group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss (FVPL), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss.

Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payment of principal and interest.

Debt instruments

Subsequent measurement of debt instruments depends on the group's business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which the group classifies its debt instruments:

- **Amortised cost:** Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortised cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on derecognition is recognised directly in profit or loss and presented in other gains/(losses), together with foreign exchange gains and losses. Impairment losses are presented as separate line item in the statement of profit or loss.
- **FVOCI:** Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets' cash flows represent solely payments of principal and interest, are measured at FVOCI. Movements in the carrying amount are taken through OCI, except for the recognition of impairment gains or losses, interest revenue and foreign exchange gains and losses which are recognised in profit or loss. When the financial asset is derecognised, the cumulative gain or loss previously recognised in OCI is reclassified from equity to profit or loss and recognised in other gains/(losses). Interest income from these financial assets is included in finance income using the effective interest rate method. Foreign exchange gains and losses are presented in other gains/(losses) and impairment expenses are presented as separate line item in the statement of profit or loss.

FVPL: Assets that do not meet the criteria for amortised cost or FVOCI are measured at FVPL. Again or loss on a debt investment that is subsequently measured at FVPL is recognised in profit or loss and presented net within other gains/(losses) in the period in which it arises.

Impairment

The group assesses on a forward looking basis the expected credit losses associated with its debt instruments carried at amortised cost and FVOCI. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For trade receivables, the group applies the simplified approach permitted by AASB 9, which requires expected lifetime losses to be recognised from initial recognition of the receivables.

Foreign currency translation

(i) Functional and presentation currency

Items included in the financial statements of each of the group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency').

The consolidated financial statements are presented in Australian dollars, which is TBG Diagnostics Limited's presentation currency. TBG Inc.'s functional currency is in Taiwanese dollars converted to Australian dollars to conform to the group's presentation currency.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Foreign currency translation (cont'd)

(ii) Transactions & balances

Transactions in foreign currencies are initially recorded in the functional currency by applying the exchange rates ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the reporting date.

(iii) Translation of Group Companies functional currency to presentation currency

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate as at the date of the initial transaction. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- Monetary assets and liabilities are translated at the spot rate of exchange at reporting date.
- income and expenses are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions), and
- all resulting exchange differences are recognised in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognised in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

- Goodwill and fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the closing rate.
- when the deferred income tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting profit or loss nor taxable profit or loss; or

(iv) Translation of Group Companies functional currency to presentation currency (cont'd)

- when the taxable temporary difference is associated with investments in subsidiaries, and the timing or the reversal of the temporary difference can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Income tax

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the reporting date.

Deferred income tax is provided on all temporary differences at the reporting date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax liabilities are recognised for all taxable temporary differences except:

- when the deferred income tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting profit or loss nor taxable profit or loss; or
- when the taxable temporary difference is associated with investments in subsidiaries, and the timing or the reversal of the temporary difference can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Income tax (cont'd)

Deferred income tax assets are recognised for all deductible temporary differences, carry-forward of unused tax credits and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry-forward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred income tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- when the deductible temporary difference is associated with investments in subsidiaries, in which case a deferred tax asset is only recognised to the extent that it is probable that the temporary difference will reverse in the foreseeable future and taxable profit will be available against which the temporary difference can be utilised.

The carrying amount of deferred income tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilised.

Unrecognised deferred income tax assets are reassessed at each reporting date and are recognised to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset only if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred tax assets and liabilities relate to the same taxable entity and the same taxation authority.

Other taxes

Value Added Taxes (Including Goods and Services Tax)

Revenues, expenses and assets are recognised net of the amount of Value Added Tax (VAT), except where the amount of VAT is not recoverable from the relevant tax authority. In these circumstances the VAT is recognised as part of the cost of acquisition of the asset or as part of the item as expense. Receivables and payables are stated with the amount of VAT included. The net amount of VAT recoverable from, or payable to, the relevant tax authority is included as a current asset or liability in the statement of financial position.

Cash flows are included in the statement of cash flows on a gross basis. The VAT components of the cash flows arising from investing and financing activities which are recoverable from, or payable to, the relevant tax authority are classified as operating cash flows.

Revenues, expenses and assets are recognised net of the amount of VAT except:

- when the VAT incurred on a purchase of goods and services is not recoverable from the taxation authority, in which case the VAT is recognised as part of the cost of acquisition of the asset or as part of the expense item as applicable; and
- receivables and payables, which are stated with the amount of VAT included.

The net amount of VAT recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the statement of financial position.

Commitments and contingencies are disclosed net of the amount of VAT recoverable from, or payable to, the taxation authority.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Inventories

Inventories are stated at the lower of cost or net realisable value. Cost is determined using the weighted average method. The cost of finished goods and work in progress comprises raw materials, direct labour, other direct costs and related production overheads (allocated based on normal operating capacity). It excludes borrowing costs. The item by item approach is used in applying the lower of cost or net realisable value. Net realisable value is estimated selling price in the ordinary course of business, less the estimated cost of completion and applicable variable selling expenses.

Non-current assets (or disposal groups) held for sale and discontinued operations - refer note 4

Non-current assets (or disposal groups) are classified as held for sale if their carrying amount will be recovered principally through a sale transaction rather than through continuing use and a sale is considered highly probable. They are measured at the lower of their carrying amount and fair value less costs to sell, except for assets such as deferred tax assets, assets arising from employee benefits, financial assets and investment property that are carried at fair value and contractual rights under insurance contracts, which are specifically exempt from this requirement.

An impairment loss is recognised for any initial or subsequent write-down of the asset (or disposal group) to fair value less costs to sell. A gain is recognised for any subsequent increases in fair value less costs to sell of an asset (or disposal group), but not in excess of any cumulative impairment loss previously recognised. A gain or loss not previously recognised by the date of the sale of the non-current asset (or disposal group) is recognised at the date of derecognition.

Non-current assets (including those that are part of a disposal group) are not depreciated or amortised while they are classified as held for sale. Interest and other expenses attributable to the liabilities of a disposal group classified as held for sale continue to be recognised.

Non-current assets classified as held for sale and the assets of a disposal group classified as held for sale are presented separately from the other assets in the statement of financial position. The liabilities of a disposal group classified as held for sale are presented separately from other liabilities in the statement of financial position.

A discontinued operation is a component of the entity that has been disposed of or is classified as held for sale and that represents a separate major line of business or geographical area of operations, is part of a single co-ordinated plan to dispose of such a line of business or area of operations, or is a subsidiary acquired exclusively with a view to resale. The results of discontinued operations are presented separately in the statement of profit or loss and other comprehensive income.

Plant and equipment – refer to note 6

Plant and equipment is stated at cost less accumulated depreciation and any accumulated impairment losses.

Depreciation is calculated on a straight-line basis over the estimated useful life of the assets as follows:

Machinery & office equipment	3 to 15 years
Leasehold improvements	Shorter of rental period and useful life
Motor vehicles	4 to 5 years
Testing equipment	3 to 5 years

The assets' residual values, useful lives and amortisation methods are reviewed, and adjusted if appropriate, at each financial year end.

(i) Impairment

The carrying values of plant and equipment are reviewed for impairment at each reporting date, with recoverable amount being estimated when events or changes in circumstances indicate that the carrying value may be impaired.

The recoverable amount of plant and equipment is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Plant and equipment – refer to note 6 (cont'd)

For an asset that does not generate largely independent cash inflows, recoverable amount is determined for the cash-generating unit to which the asset belongs, unless the asset's value in use can be estimated to be close to its fair value.

An impairment exists when the carrying value of an asset or cash-generating units exceeds its estimated recoverable amount. The asset or cash-generating unit is then written down to its recoverable amount.

(ii) Derecognition and disposal

An item of plant and equipment is derecognised upon disposal or when no further future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in profit or loss in the year the asset is derecognised.

Intangibles

Research and development costs

Research costs are expensed as incurred. An intangible asset arising from development expenditure on an internal project is recognised only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability or resources to complete the development and the ability to measure reliably the expenditure attributable to the intangible asset during its development. The expenditure capitalised comprises all directly attributable costs, including costs of materials, services, direct labour and an appropriate proportion of overheads.

Other development expenditures that do not meet these criteria are recognised as an expense as incurred. Development costs previously recognised as an expense are not recognised as an asset in a subsequent period. Following the initial recognition of the development expenditure, the cost model is applied requiring the asset to be carried at cost less any accumulated amortisation and accumulated impairment losses. Any expenditure so capitalised is amortised over the period of expected benefit from the related project on a straight-line basis.

Patents

Patents acquired as part of a business combination are recognised separately from goodwill. The patents are carried at their fair value at the date of acquisition less accumulated amortisation and impairment losses. Amortisation is calculated based on the patent expiry dates on a straight-line basis.

Goodwill

Goodwill represents the excess of the cost of an acquisition over the fair value of the Group's share of the net identifiable assets of the acquired subsidiary/business at the date of acquisition. Goodwill on acquisition is included in intangible assets. Goodwill is not amortised. Instead, goodwill is tested for impairment annually or more frequently if events or circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. Goodwill is allocated to cash generating units for the purposes of impairment testing. The allocation is made to those cash generating units or groups of cash generating units that are expected to benefit from business combination in which goodwill arose, identified according to operating segments or components of operating assets.

Trade and other payables

Trade payables and other payables are carried at amortised cost and their fair value approximates their carrying value due to their short term nature. They represent liabilities for goods and services provided to the Group prior to the end of the financial year that are unpaid and arise when the Group becomes obliged to make future payments in respect of the purchase of these goods and services.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Provisions

Provisions are recognised when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

When the Group expects some or all of a provision to be reimbursed, for example under an insurance contract, the reimbursement is recognised as a separate asset but only when the reimbursement is virtually certain. The expense relating to any provision is presented in the statement of comprehensive income net of any reimbursement. If the effect of the time value of money is material, provisions are discounted using a current pre-tax rate that reflects the risks specific to the liability.

When discounting is used, the increase in the provision due to the passage of time is recognised as a borrowing cost.

Employee leave benefits

(i) Wages, salaries, annual leave and sick leave

Liabilities for wages and salaries, including non-monetary benefits expected to be settled within 12 months of the reporting date are recognised in other payables in respect of employees' services up to the reporting date. Annual leave accrued and expected to be settled within 12 months of the reporting date is recognised in current provisions. They are measured at the amounts expected to be paid when the liabilities are settled. Liabilities for non-accumulating sick leave are recognised when the leave is taken and are measured at the rates paid or payable.

(ii) Long service leave

The liability for long service leave is recognised in the provision for employee benefits and measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures, and periods of service. Expected future payments are discounted using market yields at the reporting date on national corporate bonds with terms to maturity and currencies that match, as closely as possible, the estimated future cash outflows.

Share-based payment transactions

(i) Equity-settled transactions:

The Group provides benefits to employees (including senior executives) and consultants of the Group in the form of share-based payments, whereby employees and consultants render services in exchange for shares or rights over shares (equity-settled transactions).

The cost of these equity-settled transactions is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value of rights over shares is determined using a binomial, other appropriate model. The fair value of shares is determined by the market value of the Group's shares at grant date.

In valuing equity-settled transactions, no account is taken of any performance conditions, other than conditions linked to the price of the shares of the Group (market conditions) if applicable.

The cost of equity-settled transactions is recognised, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled, ending on the date on which the relevant employees become fully entitled to the award (the vesting period).

The cumulative expense recognised for equity-settled transactions at each reporting date until vesting date reflects

- (i) the extent to which the vesting period has expired; and
- (ii) the Group's best estimate of the number of equity instruments that will ultimately vest.

No adjustment is made for the likelihood of market performance conditions being met as the effect of these conditions is included in the determination of fair value at grant date. The income charge or credit for a period represents the movement in cumulative expense recognised as at the beginning and end of that period.

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

Share-based payment transactions (cont'd)

No expense is recognised for awards that do not ultimately vest, except for awards where vesting is only conditional upon a market condition.

If the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payment arrangement, or is otherwise beneficial to the employee, as measured at the date of modification.

If an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. However, if a new award is substituted for the cancelled award and designated as a replacement award on the date that it is granted, the cancelled and new award are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share.

Contributed equity

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Earnings per share

Basic earnings per share is calculated as net profit attributable to members of the Group, adjusted to exclude any costs of servicing equity, divided by the weighted average number of ordinary shares, adjusted for any bonus element.

Diluted earnings per share is calculated as net profit attributable to members of the Group, adjusted for:

- costs of servicing equity;
- the weighted average number of additional ordinary shares that would have been outstanding assuming the conversion of all dilutive potential ordinary shares;
- the after tax effect of dividends and interest associated with dilutive potential ordinary shares that have been recognised as expenses; and
- other non-discretionary changes in revenues or expenses during the period that would result from the dilution of potential ordinary shares divided by the weighted average number of ordinary shares and dilutive potential ordinary shares, adjusted for any bonus element.

Operating segments – refer note 2

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker is responsible for allocating resources and assessing performance of the operating segments, has been identified as the chief executive officer.

NOTE 2 - OPERATING SEGMENTS

The Company operates in the biotechnology industry. The Company's activities comprise the research, development, and manufacture of biopharmaceuticals. The operating segments are identified by executive management (chief operating decision makers) based on the nature of the activity.

Accordingly, management currently identifies the Company as having one reportable segment, the InVitro Diagnostics segment which is engaged with the research of biological drugs and the retail and wholesale of veterinary drugs with operations mainly in Taiwan and China. All revenue derived from continuing operations is from the InVitro Diagnostics segment and this is what has been reported in the financial statements.

The legal parent is domiciled in Australia. The amount of its revenue from external customers in Australia is \$nil (2019: nil).

Segment revenues are allocated based on the country in which the customer is located.

The legal parent is domiciled in Australia. The amount of its revenues from external customers in Australia is \$nil (2019: \$nil). Total revenues of \$4,605,983 (2019: \$3,345,592) were derived from Taiwan.

Revenues of \$3,312,345 (2019: \$2,235,468) were derived from four regular customers composing 72% (2019: 65% from four regular customers) of total revenues for the group.

Out of total revenues, \$2,464,180 (2018: \$1,315,053) was derived from related parties in Taiwan and in China. This revenue is attributable to the In Vitro Diagnostics segment. Intersegment transactions of \$116,674 (2019: \$222,273) were eliminated pertaining to revenues and costs within the group.

Non-current assets located in Australia is \$5,852 (2019: \$905) and non-current assets located overseas is \$3,694,409 (2019: \$4,424,268) Segment assets are allocated to countries based on where the assets are located.

NOTE 3 - REVENUE AND EXPENSES

	Consolidated	
	12 months ended 31 Dec 2020	12 months ended 31 Dec 2019
	\$	\$
(a) Revenue		
Sales revenue	4,341,730	3,066,839
Technical services revenue	264,253	278,753
Total revenue from continuing operations	4,605,983	3,345,952
(b) Other income		
Reversal of loss allowance	352,400	-
Fair value gain on financial asset ¹	153,695	-
Government grant income	54,960	-
Interest and other	29,803	97,763
Foreign exchange gain	-	63,100
Total other income	590,858	160,863
(c) Depreciation		
Depreciation – continuing operations	556,467	552,778
Depreciation – discontinued operations	-	252,270
Depreciation – right-of-use assets	216,904	183,695
	773,371	988,743
(d) Minimum lease payments – operating leases		
Low value/short term leases	122,253	127,180
(e) Employee benefit expenses		
Wages and salaries	1,587,411	1,651,465
Annual and long service leave provision	12,354	8,507
Share-based payment expense	7,249	110,276
(f) Interest and finance costs		
Bank charges	11,827	9,372
Interest and finance charges paid for lease liabilities	41,136	14,108
(g) Impairment		
Impairment - investment	75,000	5,027,440
Impairment - receivables	141,189	1,861,11
	216,189	6,888,651

NOTE 3 - REVENUE AND EXPENSES (cont'd)

¹ Significant estimate – Unlisted equity investment in Zucero

Other income of \$153,695 pertained to the 2,500,000 ordinary shares transferred by Seabreeze on 9 December 2020. As described in note 1, the Group obtained an external valuation using the Available Price Methodology that adopted a value of \$1,052,252. The key assumptions used in the valuation are as follows:

- Discount rate adopted in the bond formula of 40%;
- Net present value of the debt component of the credit notes;
- The volatility adopted in the Black Sholes formula applicable to the embedded derivative and options of 91.5%; and
- The implied share price adopted in the Black Scholes formula applicable to the embedded derivative and options which is determined to be in the range of \$0.08418, \$0.07214 and \$0.06675

NOTE 4 - DISCONTINUED OPERATIONS

(i) Disposal of TBG Biotechnology Co. (Xiamen) Inc.

On 3 May 2019, the Group announced that it has completed the acquisition of Changsha ChangYe Medical Laboratory Corp. ("ChangYe") through its subsidiary TBG Biotechnology Xiamen ("TBG Xiamen") in accordance with the terms announced to ASX on 17 December 2018.

After completion of the transactions, the Company currently holds 46.65% of the equity in TBG Xiamen and TBG Xiamen holds 100% of the equity in ChangYe, such that the Company indirectly holds an interest of 46.65% in ChangYe.

The disposal resulted to a gain of \$5,843,126 which formed part of the discontinued operations and net cash outflow of \$327,534 in prior year. Following the disposal of TBG Xiamen, the 46.65% retained investment in TBG Xiamen has been accounted for as investment in equity accounted for under the equity method as required by the *Australian Accounting Standards Board (AASB) 128 Investment in Associates and Joint Ventures*.

The Groups' shareholding interest in TBG Xiamen has been changed to 48.23% from 46.65% following its rights issue participation in August 2019.

Refer to *note 12* for further details of the investment in associates accounted for under the equity method.

(ii) Disposal of Progen PG500 Series Pty Ltd

On 3 May 2019, the Company announced that it has entered into a Deed of Settlement with Zucero on 1 May 2019 for the full settlement of the \$5,999,000 deferred consideration payable by Zucero following the purchase of shares in the capital of Progen PG500 Series Pty Ltd from the Company under the Share Sale Agreement executed on 22 August 2016. Pursuant to the Deed of Settlement, the Company received \$1,999,000 cash and 10,000,000 preference shares in Zucero at an issue price of \$0.40 per share with a total value of \$4,000,000 as full settlement of the deferred consideration. Following the issuance of the preference shares, the Company holds 7.89% in the capital of Zucero.

Interest and other income from impairment reversal and gain on early settlement of \$5,999,000 deferred consideration was recognised as part of discontinued operations in prior year.

On 30 November 2020, the Company and Zucero executed a Deed of Conversion Notice whereby the Company agreed that the Company's preference shares in Zucero will be converted to ordinary shares pursuant to the Preference Share Terms set out in the Deed of Settlement entered into by the Company on 1 May 2019, subject to Zucero satisfying a number of conditions with regards to Zucero's intended listing on the ASX in the first half of calendar year 2021 (including in particular Zucero being granted conditional approval to list on ASX).

Contemporaneously with the entry into the Deed of Conversion Notice, the Company, Zucero, Seabreeze Fire Pty Ltd ("Seabreeze") and Christopher Burrell also entered into a deed pursuant to which there were mutual releases and under which, in consideration of the Company entering into the Deed of Conversion Notice, Seabreeze agreed to transfer to the Company 2,500,000 fully paid ordinary shares in Zucero (in addition to the Preference Shares).

On 31 December 2020, the Company holds 10,000,000 preference shares and 2,500,000 ordinary shares in Zucero representing 9.6% in the capital of Zucero.

NOTE 4 - DISCONTINUED OPERATIONS (cont'd)

Refer to *note 5* for details of financial assets measured at fair value through other comprehensive income.

5. FAIR VALUE MEASUREMENTS

Fair value measurements at 31 December 2020	Level 1	Level 2	Level 3	Total
	\$	\$	\$	\$
Financial assets measured at fair value through other comprehensive income				
- Ordinary shares – exploration sector ¹	-	-	-	-
- Preference and ordinary shares – biotechnology sector ²	-	1,052,242	-	1,052,242
	-	1,052,242	-	1,052,242
Fair value measurements at 31 December 2019	Level 1	Level 2	Level 3	Total
	\$	\$	\$	\$
Financial assets measured at fair value through other comprehensive income				
- Preference shares – biotechnology sector	-	4,000,000	-	4,000,000

¹ On 28 February 2020, the Group acquired 3.2% investment in the equity capital of Lanka Graphite Limited (LGR) consisting of 3,750,000 shares at \$0.02 per share for a total of \$75,000 via its participation in LGR's initial placement as part of a proposed acquisition of an Australian unlisted biopharmaceutical company by LGR. As disclosed in the Heads of Agreement dated 31 January 2020, the parties in the agreement have acknowledged that the trading of the ordinary shares in LGR on the official list of ASX has been suspended from 3 August 2018. The acquisition did not proceed.

Lanka Graphite Limited is an Australian-based Graphite Exploration Company focused on exploring high purity vein graphite in Sri Lanka of which has been ceased during the period. It currently holds seven exploration licences and one exploration licence application.

LGR has been actively and currently exploring acquisition opportunities across other sectors outside mining and exploration business. LGR is a related party of the Company.

On 3 August 2020, LGR has been delisted on the Australian Stock Exchange (ASX). On this basis, the investment in LGR has been impaired at 31 December 2020.

²The fair value amount is determined based on an implied share price in Zucero's most recent capital raising transaction in June 2020 which resulted to a fair value loss on financial asset at FVTOCI of \$3,101,453 pertaining to the 10,000,000 preference shares.

Under a Deed of Settlement dated 30 November 2020, an off-market share transfer of 2,500,000 ordinary shares in Zucero was made by Seebreeze to TBG on 9 December 2020 resulting to a total fair value of the financial assets to \$1,052,242. The corresponding increase in the fair value by \$153,695 has been recognised as income in the Statement of Profit & Loss.

On 31 December 2020, TBG holds 10,000,000 preference shares and 2,500,000 ordinary shares in Zucero.

Adopting the Available Price Methodology, the factors contributing to the significant decline in the implied fair value of the financial asset from 31 December 2019 include:

- The assumptions made to determine the implied share price of the financial asset with respect to convertible notes, call options and embedded derivative as issued under Zucero's most recent capital raising transaction, as described in note 2;
- The additional capital required to progress Zucero's medical research activities in relation to its lead product, Pixatimod and COVID19; and
- The current market conditions to raise capital is challenging due to uncertainty relating to COVID19. It is always challenging to raise capital for high risk-reward investment opportunities and an investment in Zucero's business is considered high risk-reward. Therefore, high yield and/or substantial discounts are required to entice potential investors to invest in Zucero.

5. FAIR VALUE MEASUREMENTS (cont'd)

The Group has classified its financial instruments into the three levels prescribed under the Australian Accounting Standards. An explanation of each hierarchy and the valuation techniques used to determine their fair values are as follows:

Level 2

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. The fair value of financial instruments determined using valuation techniques which maximises the use of observable market data and with little reliance on entity-specific estimates. The fair value of the Group's financial asset is determined using the Available Market Prices valuation methodology. The selection of this method was assessed by the Group as the most appropriate valuation methodology based on readily observable market transactions.

Financial assets at fair value through other comprehensive income comprise equity securities which are not held for trading, and which the group has irrevocably elected at initial recognition to recognise in this category. These are strategic investments and the group considers this classification to be more relevant. Refer to *note 4 (ii)* –for details of the financial asset measured at fair value through other comprehensive income. Gains and losses relating to these financial assets recognised in this category will be recognised in other comprehensive income.

On disposal of the investment, any related balance within the FVTOCI reserve will be transferred to profit and loss.

Level 3

Level 3 inputs are based on unobservable market data for the asset or liability.

NOTE 6 - NON-CURRENT ASSETS - PLANT & EQUIPMENT

	Consolidated	
	31 Dec	31 Dec
	2020	2019
	\$	\$
Machinery & equipment at cost	1,383,890	1,329,631
Accumulated depreciation	(1,067,018)	(919,851)
	316,872	409,780
Testing equipment at cost	2,532,762	2,567,913
Accumulated depreciation	(2,178,518)	(1,883,452)
	354,244	684,461
	671,116	1,094,241

NOTE 6 - NON-CURRENT ASSETS - PLANT & EQUIPMENT (cont'd)

Movements in carrying amounts

	Machinery & office equipment \$	Testing equipment \$	Motor vehicles \$	Leasehold improvements \$	Total \$
Consolidated					
At 1 January 2019	599,213	845,866	-	-	1,445,079
Exchange differences	22,728	14,559	76	13,380	50,743
Additions – external	67,014	174,279	-	29,864	271,157
Depreciation	(291,614)	(350,243)	-	(163,191)	(805,048)
Assets classified as held for sale and other disposals - note 4 (i)	12,439	-	(76)	119,947	132,310
At 31 December 2019	409,780	684,461	-	-	1,094,241
At 1 January 2020	409,780	684,461	-	-	1,094,241
Exchange differences	(542)	3,682	-	-	3,140
Additions – external	89,999	40,203	-	-	130,202
Depreciation	(182,365)	(374,102)	-	-	(556,467)
At 31 December 2020	316,872	354,244	-	-	671,116

NOTE 7 - BORROWINGS

	Consolidated 31 Dec 2020 \$	31 Dec 2019 \$
Short-term borrowing ¹	2,772,600	952,140
Long-term borrowing ²	449,264	-

¹ The total short-term bank borrowings of \$2,772,600 (TW\$ 50 million) bears an interest rate ranging from 1.75% to 1.9% per annum and are payable within six (6) months to one (1) year.

² The long-term bank borrowing of \$449,264 (TW\$ 9.7 million) bears an interest rate of 2.5% per annum with a term of three (3) years payable in thirty-six (36) equal monthly instalment payments

NOTE 8 - CONTRIBUTED EQUITY

Consolidated	
31 Dec 2020	31 Dec 2019
\$	\$

a) Issued and paid up capital	36,211,120	36,211,120
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Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the company in proportion to the number of and amounts paid on the shares held. On a show of hands every holder of ordinary shares present at a meeting in person or by proxy, is entitled to one vote, and upon a poll each share is entitled to one vote. Ordinary shares have no par value and the company does not have a limited amount of authorised capital.

b) Movements in shares on issue

	31 December 2020		31 December 2019	
	Number of shares	Amount \$	Number of Shares	Amount \$
Beginning of the financial period	217,587,289	36,211,120	217,587,289	36,211,120
Transactions during the period:	-	-	-	-
End of the financial period	217,587,289	36,211,120	217,587,289	36,211,120

c) Share options

At 31 December 2020 there were a total of 1,500,000 (2019: 2,925,000) unissued ordinary shares in respect of which options were outstanding.

NOTE 9 - EARNINGS/(LOSS) PER SHARE

The following reflects the income and share data used in the basic and diluted earnings per share computations:

	Consolidated	
	31 Dec 2020 \$	31 Dec 2019 \$
Earnings used to calculate basic and diluted EPS	(3,548,975)	620,137
Earnings used to calculate basic and diluted EPS – continuing	(3,548,975)	(11,221,989)
Weighted average number of shares and options	Number of shares	Number of shares
Weighted average number of ordinary shares outstanding during the period, used in calculating basic earnings per share	217,587,289	217,587,289
Weighted average number of dilutive options outstanding during the period	-	-
Weighted average number of ordinary shares and potential ordinary shares outstanding during the period, used in calculating diluted earnings per share	217,587,289	217,587,289

NOTE 9 - EARNINGS/(LOSS) PER SHARE (cont'd)

Basic loss per share amounts are calculated by dividing the net loss for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year. Diluted loss per share amounts are calculated by dividing the net loss attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all dilutive potential ordinary shares into ordinary shares.

At 31 December 2020, there are 1,500,000 (2019: 2,925,000) options outstanding. Options are not considered dilutive as they are currently out of the money. Options may become dilutive in the future.

NOTE 10 - SIGNIFICANT EVENT AFTER THE REPORTING DATE**Establishment of wholly-owned subsidiary TDL Holding Co.**

On 4 February 2021, the Group established a new wholly owned offshore subsidiary, TDL Holding Co. in Cayman Islands ("TDLH") under TBG Diagnostics Limited. Under the new structure, the Company's wholly owned subsidiary in Cayman Islands, TBG Inc ("TBG Cayman"), will transfer 100% of the net assets of TBG Taiwan and TBG Texas to TDLH who will then hold 100% of the equity capital of TBG Taiwan and TBG Texas. TBG Inc will continue to hold 48.23% of the equity capital of TBG Xiamen, the group's investee company in China.

After the proposed group restructure, the equity interests of the group in the subsidiaries and associates will remain unchanged. The group still holds 100% of the equity capital of TBG Taiwan and TBG Texas and 48.23% of the equity capital of TBG Xiamen.

The purpose of the proposed group restructure is to allow TBG Inc to have freedom to serve as listing entity for Initial Public Offering (IPO) on international stock exchanges, facilitating fundraising of the group.

NOTE 11 - CASH AND CASH EQUIVALENTS

	Consolidated	
	12 months ended 31 Dec 2020	12 months ended 31 Dec 2019
Cash and cash equivalents	\$	\$
Cash at bank and on hand	2,775,032	2,152,071
Short-term deposits	1,002,156	3,053,060
Cash and cash equivalents	3,777,188	5,205,131

12. INVESTMENT IN ASSOCIATES ACCOUNTED FOR UNDER THE EQUITY METHOD

Investment in associates are accounted for under the equity method of accounting. Information relating to associates that are material to the consolidated entity are set out below:

(a) Details of associates and joint venture entities

Name	Country of Incorporation	% Equity Interest	
		31 Dec 2020	31 Dec 2019
TBG Biotechnology Corp. (Xiamen) Group	China	48.23	48.23
- Xia De (Xiamen) Biotechnology Co., Ltd	China	48.23	48.23
- TBG Biotechnology (Hunan)	China	42.87	42.87
- TBG Digital Cloud	China	48.23	48.23
- Changsha ChangYe Medical Laboratory Corp.	China	48.23	48.23
- Changsha ChangYe Medical Technology	China	47.75	47.75
- Changsha ChangYe Medical Laboratory	China	48.23	48.23
- Beijing ChangYe Medical Laboratory Ltd	China	48.23	-

(b) Financial statements of associate

Summarised Statement of Financial Position

	31 Dec 2020	31 Dec 2019
	\$	\$
Current assets	7,182,814	3,530,023
Current liabilities	7,533,678	3,312,825
Current net assets	(350,864)	217,198
Non-current assets	9,833,226	11,406,099
Non-current liabilities	-	943,272
Non-current net assets	9,833,226	10,462,827
Net assets	9,482,362	10,680,025
Accumulated NCI	42,570	45,734

12. INVESTMENT IN ASSOCIATES ACCOUNTED FOR UNDER THE EQUITY METHOD (cont'd)

(b) Financial statements of associate (cont'd)

	2020	2019
	\$	\$
Statement of Comprehensive Income		
Revenue	11,470,356	2,669,797
Cost of sales	(7,294,460)	(928,321)
Gross profit	4,175,896	1,741,476
Expenses	(5,041,673)	(5,581,951)
Results from operating activities	(865,777)	(3,840,475)
Income tax	-	-
Loss before income tax	(865,777)	(3,840,475)
Other comprehensive income	(331,886)	(1,049,763)
Total comprehensive income (loss)	(1,197,663)	(4,890,238)
Net loss attributable to non-controlling interest	(3,164)	(45,913)

(c) Reconciliation to investment in associates accounted for under the equity method

	31 Dec 2020	31 Dec 2019
	\$	\$
Opening balance, 1 January	3,143,236	-
Fair value at initial recognition – note 2	-	8,806,877
Additional cash investment from rights issue	-	2,130,184
Share of other reserves	(562,262)	(419,057)
Share of net loss of associates – (b)	(641,952) ¹	(2,347,328) ²
Impairment loss	-	(5,027,440)
Closing balance, 31 December	1,939,022	3,143,236

¹ Includes \$225,913 pertaining to share in unrealised gross profit on downstream and upstream sales, and amortisation of intangibles

² Includes \$517,211 pertaining to share in amortisation of intangibles and goodwill written-off

Authorised by:

The Board of Directors
26 February 2021