



# Market Announcement

3 March 2021

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Attached for the information of the market is ASX's query letter to TBG Diagnostics Limited (ASX:TDL) dated 8 January 2021 and TDL's response dated 1 March 2021.

ASX's enquiries are ongoing. TDL's securities will remain suspended until further notice.



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1 March 2021

Mr Corey Lian  
Adviser, ASX Listings Compliance (Sydney)  
ASX Compliance Pty Ltd

Dear Mr Lian

**Re: TBG Diagnostics Limited ('Company' or 'TDL') - Response to ASX Query Letter**

We refer to your letter dated 8 January 2021 regarding the above matter (**8 January Letter**) and respond to your queries as follows:

***Director's Interest Notice***

**1. ASX notes that:**

- **Section 10E(ii) of the Annual Report disclosed that Dr Chang held a balance of 500,000 Shares at 1 January 2019, disposed of 500,000 Shares during FY2019 ('Disposal') and, in turn, held no Shares at 31 December 2019.**
- **It appears that no Appendix 3Y was lodged in relation to the Disposal (noting that the last Appendix 3Y for Dr Chang was lodged on 5 May 2016).**

**Consequently, it appears that TDL may have breached Listing Rules 3.19A and/or 3.19B.**

**In light of the above and having regard to Listing Rules 3.19A.2 and 3.19B and Guidance Note 22: Director Disclosure of Interests and Transactions in Securities - Obligations of Listed Entities:**

**a) Please provide full details of the Disposal.**

Dr Stanley Chang did not dispose the 500,000 TDL shares during FY2019 and he is still currently the beneficial owner of the 500,000 TDL shares. Dr Chang's foreign stock account statement as of 31 December 2020 is attached to this letter as Appendix A.

In March 2019, Dr. Chang changed his stockbroker from Far Eastern International Securities to Yuanta Securities (which is using Citibank as sub-broker in Australia). After the change of stockbroker, the 500,000 TDL shares were transferred to the registry name 'Citicorp Nominees Pty Limited'. However, Dr Chang is still the beneficial owner of the 500,000 TDL shares. A share-holding record provided by Computershare as of 13 January 2021 is attached to this letter as Appendix B.

By an administrative oversight, this was not correctly identified during the preparation of the 2019 Annual Report. However, this will be corrected in the 2020 Annual Report.

**b) Please explain why an Appendix 3Y was not lodged in relation to the Disposal.**

Since there is no disposal of a beneficial interest in the TDL shares by Dr Chang, no Appendix 3Y was required to be lodged.

**c) What arrangements does TDL have in place under Listing Rule 3.19B with its directors to ensure that it is able to meet its disclosure obligations under Listing Rule 3.19A?**

TDL has adopted a Securities Trading Policy. The Securities Trading Policy imposes restrictions on TDL key management personnel dealing with TDL securities and adopts a pre-approval procedure which requires key management personnel to obtain prior written approval from TDL prior to their or their associates trading in TDL's securities.

TDL has recently reviewed and updated its governance policies, including the Securities Trading Policy and has also undertaken external legal training on both its Securities Trading Policy and Continuous Disclosure Policies with its Board and key management personnel.

**d) If the current arrangements are inadequate or not being enforced, what additional steps does TDL intend to take to ensure compliance with Listing Rule 3.19B?**

TDL believes its current arrangements are adequate to ensure its compliance with Listing Rule 3.19B, and are being well enforced. It does not consider that any additional steps are required.

***Medigen***

**2. ASX notes the following in relation to the 2015 Distribution Agreement:**

- **Medigen has been the controlling shareholder (51.76% shareholding) and ultimate parent company of TDL since 29 January 2016.**
- **Medigen has been a party to whom Listing Rule 10.1 applies since 22 May 2013.**
- **It appears to be an agreement to sell goods to a Listing Rule 10.1 party over an extended term which constitutes a disposal of those goods to a Listing Rule 10.1 party for the purposes of Listing Rule 10.1 (see section 6.5 of Guidance Note 24 in relation to term contracts).**
- **It was executed in January 2015.**
- **It does not appear to have been disclosed in the Prospectus or in the Notice.**
- **The Investor Presentation did not disclose that Medigen was one of TBG's distributors or customers.**

- Since 1 July 2016, TBG Taiwan has made sales of goods to Medigen totalling \$4,197,747, as set out in the table below. In aggregate, these sales have exceeded 5% of TDL's equity interests at 30 June 2016 (and in each reporting period thereafter). Furthermore, sales of goods to Medigen in both FY2017 and FY2018 exceeded 5% of TDL's equity interests in those respective years.

\$	2H FY2016*	FY2017	FY2018	FY2019	1H FY20	Total
Sale of goods to Medigen*	584,019	1,815,907	954,586	448,616	394,619	4,197,747
TDL's sales revenue	1,183,095	3,505,273	2,848,954	3,066,839	1,787,415	12,391,576
% of TDL's sales revenue	49%	52%	34%	15%	22%	34%
5% of TDL's equity interests**	1,049,409	749,687	592,457	642,818	456,571	

\*From related party transaction disclosures in TDL's financial statements.

\* 1 July 2016 - 31 December 2016

\*\* Calculated based on TDL's equity interests at the end of the relevant reporting period. At 30 June 2016 (the end of the first reporting period following the 2016 Reinstatement), 5% of TDL's equity interests amounted to \$1,159,383.

**Based on the information above, it appears that TDL may have breached Listing Rule 10.1 in relation to the 2015 Distribution Agreement.**

**In light of the above:**

- a) Please explain why the Company did not disclose the 2015 Distribution Agreement in the Prospectus or in the Notice.**

The 2015 Distribution Agreement was entered into between TBG Biotechnology Corp ('**TBG Taiwan**') and Medigen Biotechnology Corporation ('**Medigen**') following the transfer of the HLA (Human Leukocyte Antigen) business ('**Business**') from Medigen into TBG Taiwan in January 2015. Considering the complexity of transferring all customer contracts of the Business from Medigen to TBG Taiwan and in order to minimise the disruptions to the Business caused by the transfer, TBG Taiwan and Medigen agreed to enter into the 2015 Distribution Agreement for the purposes of maintaining the existing customers of the Business as of 31 December 2014 for the benefit of TBG Taiwan. Under the 2015 Distribution Agreement, Medigen acts as an agent of TBG Taiwan for the sale of the HLA products to Customers and retains 5% of the sales amount as an agent fee.

The agency arrangement was put in place to facilitate business continuation. In effect, it did not comprise a sale of goods from TDL to Medigen for the amount set out in the table above as Medigen only received 5% of that sales amount.

The agent fee received by Medigen is therefore relatively low and considered immaterial in the context of the product sales revenue, and hence TDL did not consider the 2015 Distribution Agreement to be a material contract for the purposes of disclosure in the Prospectus or in the Notice.

- b) Has TDL considered the application of Listing Rule 10.1 to the 2015 Distribution Agreement? If the answer to this question is 'no', why not?**

TDL does not consider Listing Rule 10.1 applies to the 2015 Distribution Agreement because the transaction between Medigen and TBG Taiwan under the 2015 Agreement is neither an acquisition of a substantial asset nor a disposal of substantial asset under Listing Rule 10.1.

Under articles 8.2 and 8.3 of the 2015 Distribution Agreement, Medigen only retains 5% of the sales amount as an agent fee for assisting TBG Taiwan with maintaining the customers of the Business and distributing the products. Therefore, the value of the consideration being paid by TBG Taiwan to Medigen

shall be 5% of the sales amount. That amount is the actual consideration that Medigen receives from the transaction, rather than the total payment of goods passed on by Medigen for the customer sale.

Therefore, the value of actual monies received by Medigen between 1 July 2016 and 30 June 2020 was 5% of the amount listed as total sale of goods to Medigen in each year. Such amount does not exceed 5% of TDL's equity interests in each reporting period.

For example, the value of consideration paid by TBG Taiwan to Medigen was \$90,795 in FY2017 and \$47,729 in FY2018 – such amount did not exceed 5% of TDL's equity interests in the relevant period.

Since the asset disposed by TBG Taiwan to Medigen in the transactions under the 2015 Distribution Agreement has not exceeded 5% of TDL's equity interests, the disposal shall not be considered substantial. Therefore, TDL does not consider Listing Rule 10.1 would apply to the 2015 Distribution Agreement.

**c) Please detail the material terms of the 2015 Distribution Agreement, and specifically note whether it includes a net profit sharing arrangement akin to the 2020 Distribution Agreement.**

The material terms of the 2015 Distribution Agreement include the following:

- The term of the agreement commences from 1 January 2015 and continues until both parties agree in writing to terminate.
- TBG Taiwan grants an exclusive right to Medigen to sell approximately 190 specified products of TBG Taiwan's to Medigen's customers.
- Medigen will retain 5% of the sales amount as an agent fee.
- Medigen will pay TBG Taiwan for the goods supplied to its customer within 30 days after receiving the payments from such customer.

The 2015 Distribution Agreement does not include a net profit sharing arrangement akin to the 2020 Distribution Agreement.

It is noted that a copy of the 2015 Distribution Agreement and its English translation have already been provided by TDL to ASX.

**3. ASX notes the following in relation to the 2015 Distribution Agreement:**

- It was entered into on 15 February 2020 and provides that Medigen is the worldwide exclusive distributor of TBG Taiwan's SARS-CoV-2 test kits (except in Australia and New Zealand).
- Medigen is party to whom Listing Rule 10.1 applies by virtue of Listing Rules 10.1.1 and 10.1.3.
- It appears to be an agreement to sell goods to a Listing Rule 10.1 party over an extended term which constitutes a disposal of those goods to a Listing Rule 10.1 party for the purposes of Listing Rule 10.1.

- **Based on the Activities Report, TBG Taiwan made sales of goods to Medigen under the 2020 Distribution Agreement of \$270,725 in the period from 15 February 2020 to 30 September 2020.**

**Given the sales to 30 September 2020 equate to 2.1% of TDL's equity interests at 31 December 2019 and the 2020 Distribution Agreement expires on 14 February 2023, it appears likely that total sales over the term of the 2020 Distribution Agreement will exceed 5% of TDL's equity interests.**

**Furthermore, TBG Taiwan received 'advance receipts' from Medigen amounting to \$1,107,717 in 1H FY20, which equate to 8.6% of TDL's equity interests at 31 December 2019.**

**Based on the information above, it appears that TDL may have breached Listing Rule 10.1 in relation to the 2020 Distribution Agreement.**

**In light of the above:**

- Did TDL consider the application of Listing Rule 10.1 to the 2020 Distribution Agreement? If the answer to this question is 'no', why not?**

The 2020 Distribution Agreement was entered into on 15 February 2020. As provided in TDL's response to ASX's query letter on 14 September 2020, the 2020 Distribution Agreement was entered into for the purposes of including the new products of TBG Taiwan (i.e. the SARS-CoV-2 related diagnostic products) into Medigen's existing distribution scope. TDL does not consider it a new and separate transaction or materially changing the pre-existing distribution relationship.

In addition, when TDL entered into the 2020 Distribution Agreement with Medigen in February 2020 for the SARS-CoV-2 related diagnostic products, Medigen had not received any confirmed purchase order from its customers. TDL is unable to forecast the sale of such products through Medigen given that the COVID-19 diagnostic products are new to TDL and the market is uncertain. Therefore, at the time when the 2020 Distribution Agreement was entered into, TDL was unable to ascertain whether the value of consideration that Medigen will receive under the agreement would exceed 5% of its equity interests.

Furthermore, as provided in the response in question 3(b), TDL believes that the value of the consideration being paid by TBG Taiwan to Medigen shall be the actual consideration that Medigen receives from the transaction, rather than the total payment of goods paid by Medigen. Under article 4.1 of the 2020 Distribution Agreement, Medigen retains 50% of the net profit generated from the sales of the SARS-CoV-2 related diagnostic products. TDL confirms that the value of the consideration retained by Medigen since 15 February 2020 until the date of this letter has not exceeded 5% of TDL's equity interests.

- Please provide a copy of the minutes of the meetings of the directors of TBG Taiwan and TDL approving the 2020 Distribution Agreement (not for release to the market).**

Since entering into distribution arrangements for the marketing and sale of TBG Taiwan's products with Medigen is part of the company's ordinary course of business and standard business practice, neither TDL nor TBG Taiwan consider the 2020 Distribution Agreement to be a matter requiring approval by their directors. Therefore, there are no minutes of the meetings of the directors approving the 2020 Distribution Agreement.

- c) **Please list the directors of TBG Taiwan and specify whether they are employed or engaged by TDL or by Medigen.**

The directors of TBG Taiwan are Dr Stanley Chang, Arlene Chiang and Fanny Hu.

Dr Chang is a non-executive director at TDL and a director and Chairman of Medigen's Board.

Arlene Chiang is not employed or engaged by TDL and is an associate vice president at Medigen.

Fanny Hu is not employed or engaged by TDL and is an executive assistant to the chairman of Medigen's Board.

**4. ASX notes that:**

- **TDL disclosed related party expenses pertaining to an office lease in its financial statements for FY2016 and FY2017.**
- **The lease agreement provided in response to question 2(i) of the March Query Letter commenced on 1 January 2018 and concluded on 31 December 2020.**

**In light of the above:**

- a) **Please provide a copy of the lease agreement which was in place with Medigen between the 2016 Reinstatement and 31 December 2017 (not for release to the market).**

The lease agreement between TDL and Medigen with a term commencing from 1 January 2015 to 31 December 2017 is attached to this letter as Appendix C.

- b) **Has the office lease been extended beyond 31 December 2020? If the answer to this question is 'yes', please provide a copy of the agreement (not for release to the market).**

Yes, the office lease between TDL and Medigen has been extended until 31 December 2021. The renewed lease agreement is attached to this letter as Appendix D.

**5. Please provide an account of TDL's understanding of the circumstances which gave rise to:**

- a) **The Taiwan Securities and Futures Bureau imposing an administrative fine on Medigen in relation to TDL's internal procedures governing acquisitions and disposals of assets (see sub-paragraph O(ii) above).**

To TDL's knowledge, this administrative fine is in relation to a requirement under the Taiwan laws and regulations which requires all listed companies and their subsidiaries to have and implement an internal procedure governing acquisition and disposal of assets.

In August 2017, TDL received a request from Medigen to accept and implement Medigen's Rules and Procedures for Acquisition or Disposal of Assets ('**Rules and Procedures**'). During the TDL Board Meeting on 21 August 2017, the TDL

Board discussed the Rules and Procedures and passed a resolution to accept the Rules and Procedures.

- b) **TPEX imposing a penalty on Medigen on 4 June 2020 for failing to follow the TPEX procedures for verification and disclosure of material information (see sub-paragraph O(iii) above).**

To TDL's knowledge, this penalty imposed on Medigen is in relation to a delayed announcement by Medigen on TDL's suspension from official quotation on 19 March 2020.

Medigen did not make any public announcement on 19 March 2020 since it did not consider TDL's suspension to have a material effect on the interest of Medigen and its' shareholders. However, at the request of TPEX, Medigen announced TDL's suspension on 28 May 2020.

6. **To TDL's knowledge, has Medigen (including its subsidiaries and associates and/or any of its officers) been the subject of any regulatory investigation, review, audit, assessment or action in Taiwan or mainland China that is not identified in paragraph O above?**

To TDL's knowledge, Medigen (including its subsidiaries and associates and/or any of its officers) has not been the subject of any regulatory investigation, review, audit, assessment or action in Taiwan or mainland China that is not identified in paragraph O of the 8 January Letter.

7. **ASX notes that:**

- **Medigen is listed on TPEX.**
- **Medigen's annual reports and financial statements for FY2018 and FY2019 ('Medigen Reports') are not currently available on Medigen's website.**

**In light of the above, please provide a copy of the following:**

- a) **the Medigen Reports; and**

Medigen's annual reports and financial statements for FY2018 and FY2019 are attached to this letter as Appendices E and F.

TDL understands from Medigen that under the law of Taiwan and TPEX's listing rule requirements, all public companies (including TPEX-listed companies) in Taiwan are required to disclose relevant information (including material information, periodic information and no-periodic information) on Market Observation Post System ('MOPS'). This is to ensure that investors have equal and timely access to material information about all listed companies. There is no requirement that TPE-x listed companies (such as Medigen) need to disclose its annual reports and financial statements on its website.

- b) **any announcements made by Medigen since 1 January 2018 which reference TDL (including its subsidiaries or associates).**

The announcements made by Medigen since 1 January 2018 which reference TDL (including its subsidiaries or associates) are attached to this letter as Appendix G.



**TBG Xiamen (TDL's interest - 48.23%)**

8. **ASX notes that TBG Taiwan has made sales to and purchases of goods and fixed assets from TBG Xiamen, as set out in the table below.**

\$	FY2019	1H FY20	Total
Sale of goods to TBG Xiamen	866,436	382,233	1,248,669
TDL's sales revenue	3,066,839	1,787,415	4,854,254
% of TDL's sales revenue	28%	21%	26%
Purchase of goods from TBG Xiamen*	-	1,157,411	
Purchase of fixed assets from TBG Xiamen	-	135,738	

Source: Related party transaction disclosures in TDL's financial statements. TBG Xiamen has been accounted for as an associate since 3 May 2019.

\*At 30 June 2020, \$692,337 was payable to TBG Xiamen and \$585,281 had been advanced to TBG Xiamen.

**In light of the above, which products did TBG Taiwan:**

- a) **sell to TBG Xiamen in FY2019 and 1H FY20?**

The products that TBG Taiwan sold to TBG Biotechnology Xiamen Inc. ('**TBG Xiamen**') in FY2019 and 1H FY20 are HLA reagents/kits (raw materials, semi-finished goods and finished goods).

- b) **purchase from TBG Xiamen in 1H FY20?**

The products that TBG Taiwan purchased from TBG Xiamen in 1H FY20 include:

- (i) HLA reagent kits;
- (ii) raw materials/consumables for the production of COVID-19 test kits and for COVID-19 research and development purposes; and
- (iii) machinery and equipment for the production of COVID-19 test kits.

9. **ASX notes that TBG Xiamen has owed a material sum of money to TDL since 30 June 2019 and that an impairment provision has been recognised against the receivables, as set out in the table below.**

\$	30 June 2019	31 December 2019	30 June 2020
Trade receivables	983,200	1,413,876	1,401,430
Other receivables	442,302	447,164	466,789
<b>Total receivables</b>	<b>1,425,502</b>	<b>1,861,040</b>	<b>1,868,219</b>
Impairment provision	-	1,861,040	1,143,848
% of TBG Xiamen receivables	-	100%	61%

Source: Related party transaction disclosures in TDL's financial statements.

**In light of the above, please explain why an impairment provision has been recognised against the amounts owing to TBG Taiwan from TBG Xiamen.**

TDL has adopted an allowance method in its consolidated accounts and the following bad debts policy for recognising the bad debts provision:

<b>Age of receivables</b>	<b>Percentage of impairment amount to be recognised</b>
up to 90 days	0
91 to 120 days	2%
121 to 180 days	10%
181 to 365 days	50%
> 365 days	100%

As to 31 December 2019, a full impairment provision of \$1,861,040 was recognised against TBG Taiwan's receivables from TBG Xiamen as the amounts have been outstanding for more than 120 days and per TBG Xiamen's cash position at 31 December 2019, it appears that it does not have sufficient cash to repay TBG Taiwan.

As to 30 June 2020, an impairment provision of 61% of the total TBG Taiwan's receivables from TBG Xiamen (that is \$1,143,848) has been recognised as most of the amounts have been outstanding for more than 120 days.

However, TBG Xiamen is profitable in FY2020. TDL believes that this demonstrates TBG Xiamen's improving capability to improve its cash flow position and repay the amounts owing to TBG Taiwan. There was a total amount of \$353,207 recovered in FY2020 pertaining to the amount impaired in FY2019.

**10. How much revenue has TBG Xiamen derived from the sale of SARS-CoV-2 test kits to date? Please include a breakdown of sales to customers in mainland China and export sales.**

The revenue that TBG Xiamen has generated from the sale of SARS-CoV-2 test kits at 31 December 2020 is AU\$ 1,790,171.

All of the sales are export sales. Accordingly, there are no sales to customers in mainland China.

**11. ASX notes that:**

- **TBG Taiwan and TBG Xiamen have separate CE mark authorisations for SARS-CoV-2 nucleic acid test kits.**
- **TBG Taiwan has CE mark authorisation for its SARS-CoV-2 IgG/IgM antibody rapid test kit.**
- **TBG Xiamen has CE mark authorisation for its SARS-CoV-2 antigen rapid test.**
- **TBG Inc has responsibility for overseeing and managing TBG Xiamen's research and development and product manufacture (see sub-paragraph J(i) above).**

**In light of the above:**

- a) Please clarify the differences (if any) between the two SARS-CoV-2 nucleic acid test kits.**

SARS-CoV-2 nucleic acid test kits and SARS-CoV-2 nucleic acid test kits are different products. The reagent used in the two test kits are different since they

are independently developed by TBG Taiwan and TBG Xiamen. There are also some other differences as listed below:

	<b>SARS-CoV-2 nucleic acid test kits developed by TBG Taiwan</b>	<b>SARS-CoV-2 nucleic acid test kits developed by TBG Xiamen</b>
Specification	96 tests/kit	24 tests/kit
Manufacturing site	Taiwan	China
Certification obtained	CE mark, US EUA, Taiwan EUA	CE mark

**b) Did TBG Inc/TBG Taiwan develop the SARS-CoV-2 nucleic acid and antigen rapid test kits for TBG Xiamen?**

No, the SARS-CoV-2 nucleic acid and antigen rapid test kits were independently developed by TBG Xiamen. Neither TBG Inc. nor TBG Taiwan was involved in the development of TBG Xiamen's SARS-CoV-2 nucleic acid and antigen rapid test kits

Under the joint venture agreement entered into between TBG Inc., TBG Xiamen and others in 2018, TBG Inc. has the responsibility for overseeing and managing TBG Xiamen's research and development and product manufacturing activities. However, TBG Inc. is not normally involved in the day-to-day operations of TBG Xiamen's business which includes the research and development of specific products and which also includes the development of the SARS-CoV-2 nucleic acid and antigen rapid test kits.

Moreover, the SARS-CoV-2 nucleic acid and antigen rapid test kits do not fall under the licensing agreement between TBG Taiwan and TBG Xiamen.

**c) What sales protocols and procedures (if any) have been established between TBG Taiwan and TBG Xiamen regarding the sales and export of the abovementioned SARS-CoV-2 test kits into territories such as Europe?**

TBG Taiwan and TBG Xiamen have their own sales team and channels and different target markets. There is neither a sales protocol nor procedure established between the two companies.

Specifically, the selling price of TBG Taiwan's SARS-CoV-2 test kits is higher than that of TBG Xiamen's SARS-CoV-2 test kits. TBG Taiwan's SARS-CoV-2 test kits target high-end markets and customers, and TBG Xiamen's SARS-CoV-2 test kits target low-end markets and customers.

**12. Does Medigen have any distribution arrangements in place with TBG Xiamen (or any of its subsidiaries)? If the answer to this question is 'yes', please provide a copy of the agreement (not for release to the market) and detail the material terms of the agreement.**

No, there is no distribution arrangements in place between Medigen and TBG Xiamen.

**13. Is the licensing agreement between TBG Taiwan and TBG Xiamen still on foot (see sub-paragraph J(ii) above)?**

Yes, the licensing agreement between TBG Taiwan and TBG Xiamen entered into on or about 1 December 2017 is still on foot.

**14. Who are TBG Xiamen's three supervisors (see sub-paragraph J(i) above)?**

The three supervisors of TBG Xiamen are Fanny Hu, Xu Xue-Lian and Guo Feng.

**15. Please provide a copy of the external valuation report for TBG Xiamen (see sub-paragraph K(v) above) (not for release to the market).**

A copy of the external valuation report for TBG Xiamen is attached to this letter as Appendix H.

***Customers and other arrangements***

**16. Please identify:**

**a) the regular customers (other than Medigen and TBG Xiamen) referred to in sub-paragraphs I(ii) and K(vi) above; and**

University of Texas MD Anderson Cancer Centre ('**MD Anderson**') is the regular customer (other than Medigen and TBG Xiamen) referred to in TDL's FY2018 annual report. MD Anderson is based in the United States, rather than Taiwan.

Buddhist Tzu Chi Medical Foundation Hualien Tzu Chi Hospital and Cornell Corporation are the regular customers (other than Medigen and TBG Xiamen) referred to in TDL's FY2019 annual report. These two customers are based in Taiwan.

**b) the 'major sales distributor' referred to in sub-paragraph I(i) above.**

The 'major sales distributor' referred to in TDL's FY2018 annual report is a distributor in the Middle East.

TDL does not consider the distribution agreement with this distributor to be material and needing disclosed to the market because the revenue derived from the sale of goods to this distributor by TDL did not exceed 5% of TDL's equity interests in FY 2018. The distribution agreement was entered in the ordinary course of TDL's business.

**17. Please provide details of the collaboration arrangements and product licensing agreements that TDL entered into with external parties in FY2019 (see sub-paragraph K(i) above).**

The collaboration arrangements and product licensing agreements between TDL and external parties referred to in TDL's FY2019 annual report are as follows:

- **Omixon Distribution Agreement**

TBG Taiwan and Omixon Ltd ('**Omixon**') entered into a distribution agreement on 8 November 2016 and a deed of variation on 21 November 2016.

The key terms of the agreement are as follows:

- (i) TBG Taiwan becomes the exclusive distributor of Omixon's Holotype HLA typing products within China, Hong Kong, Taiwan and Australia.
- (ii) TBG Taiwan has the right to market, promote and sell the relevant Omixon products within the territory.

- (iii) Omixon is responsible for the manufacturing of the products and provide assistance to TBG Taiwan on the marketing and sales of the products.
- (iv) The initial term of the agreement is 1 year commencing on the date of the agreement, and will be automatically renewed for succeeding terms of 1 year each unless terminated by either party by written notice at least 60 days prior to the expiration of any term.
- (v) Working together with Omixon, TBG Taiwan has added the Holotype HLA typing products to its existing HLA typing solutions.

- **Exclusive Distribution Agreement with a Distributor in Turkey**

TBG Taiwan entered into an exclusive distribution agreement with a distributor in Turkey ('**Turkey Distributor**') on 5 February 2018.

The key terms of the agreement are as follows:

- (i) The Turkey Distributor becomes the exclusive distributor of TBG Taiwan's HLA typing kits in Turkey.
- (ii) The Turkey Distributor has the right to promote, advertise, market, propose, accept bids, distribute and sell the products within the territory.
- (iii) TBG Taiwan is responsible for providing the products, relevant training and promotional materials to the Turkey Distributor.
- (iv) The initial term of the agreement is 1 year commencing on the date of the agreement, and will be automatically renewed for succeeding terms of 1 year each based on the sales performance of the Turkey Distributor, unless either party gives written notice to the other of the desire to terminate the agreement.

- **General Distribution Contract between TBG Taiwan and TBG Xiamen**

TBG Taiwan entered into a general distribution contract with TBG Xiamen on 1 January 2017.

The key terms of the agreement are as follows:

- (i) TBG Xiamen becomes the exclusive distributor of TBG Taiwan's HLA typing kits in Mainland China (excluding Hong Kong and Macau).
- (ii) TBG Xiamen has the right to sell the products and grant sublicense to third parties within the territory.
- (iii) The parties shall renegotiate the product price and annual minimum purchase quantity once per two years.
- (iv) The initial term of the contract is 5 years commencing from 1 January 2017, and will be automatically renewed for additional 5 years upon the expiration of the initial term unless terminated by either party.

- **Exclusive License & Technology Transfer Contract between TBG Taiwan and TBG Xiamen**

TBG Taiwan entered into an exclusive license & technology transfer contract with TBG Xiamen on 1 December 2017.

The key terms of the agreement are as follows:

- (i) TBG Taiwan transfers the exclusive licensing and technology of 20 of its molecular diagnostic technologies specified in the contract to TBG Xiamen.
- (ii) TBG Xiamen has the right to use, manufacture, sell, offer to sell, import and export the licensed products within Mainland China (excluding Hong Kong and Macau).
- (iii) The term of the contract is from 1 December 2017 to 31 December 2040.

***Other***

**18. Please confirm that TDL is complying with the Listing Rules and, in particular, Listing Rule 3.1.**

TDL confirms that it is complying with the Listing Rules and, in particular, Listing Rule 3.1.

**19. Please confirm that TDL's responses to the above questions and requests have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of TDL with delegated authority from the board to respond to ASX on disclosure matters.**

TDL confirms that its responses to the above questions and requests have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of TDL with delegated authority from the board to respond to ASX on disclosure matters.

Jitto Arulampalam  
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Executive Chairman

On behalf of the Board of Directors  
TBG Diagnostics Limited



8 January 2021

Reference: 29147

Mr Justyn Stedwell  
Company Secretary  
TBG Diagnostics Limited  
Level 27  
101 Collins Street  
Melbourne VIC 3000

By email

Dear Mr Stedwell

**TBG Diagnostics Limited ('TDL' or the 'Company')<sup>1</sup>: Query Letter**

ASX Limited ('ASX') refers to the following:

- A. The Company's notice of annual general meeting and notice of general meeting dated 4 November 2015 ('Notice') which included the Explanatory Memorandum and Independent Expert's Report in relation to the Company's proposed acquisition of TBG Inc ('TBG') from Medigen Biotechnology Corp. ('Medigen') in consideration for the issue of 101,722,974 shares in the Company ('Shares') to Medigen at a deemed issue price of \$0.21 per Share, and included the following statements:
  - (i) *'TBG was founded by Medigen in 2006 and is incorporated in the Cayman Islands. TBG has three wholly owned subsidiaries: Texas Biogene, Inc. (Texas Biogene), TBG Biotechnology Corp. (TBG Taiwan) and TBG Biotechnology Xiamen Inc. (TBG Xiamen), which are based in the US, Taiwan and China respectively.'*
  - (ii) *'On 1 January 2015, Medigen's HLA business, including all employees, assets and intellectual property was transferred into TBG Taiwan.'*
- B. The Company's prospectus dated 10 November 2015 ('Prospectus') which disclosed several material contracts in section 15 including the share sale and purchase agreement in relation to the proposed acquisition of TBG ('Acquisition Agreement').<sup>2</sup>
- C. The appointment of Dr Stanley Chang, the Chairman of Medigen, as a director of the Company on 7 December 2015.
- D. TDL's announcement titled 'Company Update' released on the ASX market announcements platform ('MAP') on 29 January 2016 which disclosed, amongst other things, that the Company's acquisition of TBG had been completed.
- E. The reinstatement of the Company's securities to official quotation on 3 February 2016 following re-compliance with Chapters 1 and 2 of the Listing Rules ('2016 Reinstatement').
- F. The Form 604 (Notice of change of interest of substantial holder) lodged on MAP on 3 February 2016 which disclosed that Medigen's relevant interest in TDL had increased from 10,892,964 Shares (19.70%

<sup>1</sup> The Company's name changed from 'Progen Pharmaceuticals Limited' to 'TBG Diagnostics Limited' on 11 December 2015.

<sup>2</sup> The other material agreements were (a) an agency agreement between TBG Taiwan and Kornell Trading Co., Ltd., (b) an assignment agreement under which Medigen assigned all of its rights and duties under a development agreement with Industrial Technology Research Institute to TBG Taiwan, (c) two construction and decoration contracts for the administration, R&D and examination buildings of TBG Xiamen, (d) an equity transfer agreement to sell TBG's equity in Shanghai Haoyuan Biotech Co., Ltd., (e) an executive service agreement, (f) letters of appointment for proposed non-executive directors, and (g) deeds of indemnity, insurance and access with directors.

- voting power) to 112,615,938 Shares (51.76% voting power) on 29 January 2016 following the issue of the Shares under the Acquisition Agreement.
- G. The Appendix 3Y for Dr Stanley Chang lodged on MAP on 5 May 2016 which disclosed that Dr Chang acquired 500,000 Shares on 11 January 2016.<sup>3</sup>
- H. TDL's announcement titled 'Investor Presentation' released on MAP on 16 May 2016 which included a slide listing TBG's 'Clients and Distributors' including its 'Top Tier Clients' ('Investor Presentation').<sup>4</sup>
- I. TDL's annual report for the financial year ended 31 December 2018 (FY2018), which was released on MAP on 26 March 2019 and included the following disclosures (emphasis added):
- (i) On page 17: *'Total revenues earned during the year decreased 8.7% to \$3,152,830 in 31 December 2018 (2017: \$3,451,379). The decline in sales revenues were mainly attributed to sales rebate incentives granted to a major sales distributor for having met the agreed sales targets ... Of the sales revenue from customers, 30% (2017: 53%) represent sales to its parent entity, Medigen.'*
  - (ii) On page 50: *'Revenues of \$1,473,433 (2017: \$2,272,800) were derived from two regular customers in Taiwan composing 46.7% (2017: 56.5%) of total revenues for the group.*  
*Out of total revenues, \$954,586 (2017: \$1,815,907) was derived from a related party in Taiwan.'*
- J. ASX's query letter dated 24 March 2020 and TDL's response dated 14 April 2020 ('March Query Letter'), released together on MAP on 15 April 2020, which included the following questions (in bold) and answers (emphasis added):
- (i) **'2. Please provide copies of the following documents to ASX ...**  
**(d) the agreement(s) governing the management, governance and operations of TBG Xiamen ..., including details of TDL's involvement (if any) in the management, governance and operations of TBG Xiamen**  
  
*... Following completion of ChangYe Acquisition, the governance and overall management of TBG Xiamen and its business operations are vested in Dongyuan and the ChangYe Founding Shareholders, as provided in clause 16 of the JV Agreement, while TBG Inc retains the responsibility for overseeing and managing TBG Xiamen's research and development and product manufacture (Chapter 9 of the JV Agreement) ...*  
  
*The day-to-day management and governance of TBG Xiamen and its business operations (including formulation of policies, business plan and budgets to be applied in the conduct of the business) are in fact vested in the General Manager and Deputy General Manager(s) of TBG Xiamen, appointed by the Dongyuan and the ChangYe Founding Shareholders,*  
  
*In addition to the General Manager and the Deputy General Managers, TBG Xiamen has 3 supervisors who are responsible for the audit of the company's financial information, the TBG Xiamen board's compliance with the law and the company's policies and the enforcement of any breach or non-compliance by a director of TBG Xiamen ....'*
  - (ii) **'(g) The licensing agreement between TBG Taiwan and TBG Xiamen referred to on page 6 of the Preliminary Final Report**

<sup>3</sup> The Appendix 3Y (together with an Appendix 3Y for Ms Emily Lee) were lodged late and TDL's covering letter stated that this was 'due to inadequate internal communication and an inadvertent oversight.'

<sup>4</sup> Slide 15 stated: 'TBG's products are distributed to more than 22 countries globally' and that 'Top Tier Clients' are MD Anderson Cancer Center USA, TzuChi Bone Marrow Registry Taiwan, Center of Histocompatibility Portugal, Beijing Blood Center China, Queen Mary Hospital Hong Kong, IBTO Portugal, Russia Federal Biomedical Agency, Health Science Authority Singapore, and Milano Policlinico Hospital Italy.



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*A copy of the licensing agreement between TBG Biotechnology Corp. ('TBG Taiwan') and TBG Xiamen on or about 1 December 2017 (while both companies were still wholly subsidiaries of TDL) ('Licensing Agreement') and a certified translation are attached to this letter as Appendix E.'*

(iii) ***'(i) The office lease agreement(s) between TBG Taiwan and Medigen Biotechnology Corporation***

*A copy of the office lease agreement between TBG Taiwan and Medigen Biotechnology Corporation dated 1 January 2018 and a certified translation are attached to this letter as Appendix G ....'*

K. TDL's annual report for the financial year ended 31 December 2019 (FY2019), which was released on MAP on 15 June 2020 ('Annual Report') and included the following disclosures (emphasis added):

(i) On page 18: *'The principal activities of TBG Diagnostics Limited during the period were as follows: ... 2. Entered into collaboration arrangements and product licensing agreements with external parties to expand market presence and product portfolio ...'*

(ii) On page 21: *'...the Group increased the investment in TBG Xiamen by investing additional cash of \$2,130,184 (US\$1,430,000) through participation in rights issue. At 31 December 2019, the Groups' [sic] shareholding interest in TBG Xiamen was changed to 48.23% from 46.65% following its rights issue participation in August 2019.'*

(iii) On page 23:

- ***'CE Mark approval of TBG Xiamen's COVID-19 Virus Diagnostic Kit ...***

*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 ...*

*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.'*

- ***'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 ...*

*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.'*

(iv) Dr Stanley Chang held a balance of 500,000 Shares at 1 January 2019, disposed of 500,000 Shares during FY2019 and, in turn, held no Shares at 31 December 2019 (see section 10E(ii) of the Directors' Report on page 36).

(v) On page 48: *'In determining the fair market value of the equity accounted investment in TBG Xiamen, the Group commissioned an independent expert to obtain a valuation at 31 December 2019.'*

(vi) On page 56 (Operating segments): *'Revenues of \$2,235,468 (2018: \$1,473,433) were derived from four regular customers in Taiwan composing 65% (2018: 46.7% from two regular customers) of total revenues for the group.'*

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*Out of total revenues, \$1,315,053 (2018: \$954,586) was derived from related parties in Taiwan and in China.'*

- (vii) A receivables impairment of \$1,861,211 in FY2019 (see Note 4(g) – Impairment on page 57) with an accompanying footnote which stated:

*'The impairment of receivables is due to cash flow difficulties in the Group's investment in TBG Xiamen (refer Note 29 (a)).'*

- (viii) In Note 28(b) (Related party transactions to parent and associates) in relation to TBG Xiamen:

- Revenue from the sale of goods to TBG Xiamen of \$886,434 during FY2019.
- Trade receivables and other receivables from TBG Xiamen of \$1,413,876 and \$447,164 respectively at 31 December 2019.
- That all of the abovementioned trade and other receivables from TBG Xiamen (totalling \$1,861,040) were impaired at 31 December 2019.

- L. TDL's half year report for the six months ended 30 June 2020 (1H FY20), which was released on MAP on 31 August 2020 and included the following disclosures:

- (i) On page 6: *'Related party sales to the parent, Medigen Biotechnology Corp. amounted to \$394,693 (2019: \$425,619). Related party sales to the group's investee company, TBG Xiamen, amounted to \$382,233 (2019: \$287,964). Total related party sales composed 40.6% (2019: 41.4%) of total revenues.'*

*Other income increased 327.7% to \$435,190 (2019: \$101,747) mainly due to recovery of accounts previously impaired.'*

- (ii) 'Advance receipts' from Medigen of \$1,107,717 in 1H FY20 (see Note 11).

- (iii) In Note 11 (Related party transactions) in relation to TBG Xiamen:

- Revenue from the sale of goods to TBG Xiamen of \$382,233 during 1H FY20.
- Trade receivables and other receivables from TBG Xiamen of \$1,401,430 and \$466,879 respectively at 30 June 2020.
- That the total impairment provision relating to the receivables from TBG Xiamen was \$1,143,848 at 30 June 2020 (footnote 6).
- Purchases of goods from TBG Xiamen of \$1,157,411 during 1H FY20.
- Purchases of fixed assets from TBG Xiamen of \$135,738 during 1H FY20.
- Trade payables to TBG Xiamen of \$692,337 at 30 June 2020 for the purchase of inventories and equipment.

- M. TDL's announcement titled 'Distribution Agreement with Medigen Biotechnology Corp' released on MAP on 21 September 2020 which disclosed two distribution agreements between TBG Taiwan and Medigen, namely an agreement entered into in January 2015 ('2015 Distribution Agreement') and an agreement entered into on 15 February 2020 ('2020 Distribution Agreement'), and included the following statements (emphasis added):

*'At the request of ASX, TBG Diagnostics Limited ("TDL" or "Company") announces that its wholly owned subsidiary TBG Biotechnology Corp. ("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*

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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 ...

*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 ...*
- 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 ...*

- N. TDL’s quarterly activities report for the September 2020 quarter (‘Activities Report’), which was released on MAP on 2 November 2020 and included the following statements:

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

- O. The following information in relation to Medigen:

- (i) The article in the *Taipei Times* on 7 June 2016 titled ‘Medigen fined for failing to announce licensing deal’,<sup>5</sup> which included the following statements:

*‘The Taipei Exchange yesterday fined drugmaker Medigen Biotechnology Corp NT\$30,000 (US\$926) for failing to make a material information announcement to the public.*

*The company inked a deal extending licensing rights to China’s Jian Su Heng Rui Medicine Co to oversee sales of its new OBP-301 liver cancer medicine that was codeveloped with Japan’s Oncolys Biopharma Inc in the Chinese market on May 20.*

*However, the company failed to make an announcement at the required time; one hour before the opening of the next trading session.’*

- (ii) The Taiwan Securities and Futures Bureau advisory in relation to the administrative fine imposed on the responsible person of Medigen on 1 May 2018,<sup>6</sup> which included the following statements:

*‘Medigen Biotechnology failed to ensure that TBG Diagnostics Limited, its subsidiary, had, in accordance with the relevant regulations, established and implemented its internal procedures governing the acquisition and disposal of assets before executing the related transactions. This constitutes a violation of the aforementioned regulations.’*

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<sup>5</sup> Available at <http://www.taipeitimes.com/News/biz/archives/2016/06/07/2003648037>

<sup>6</sup> Available at [https://www.sfb.gov.tw/en/home.jsp?id=100&parentpath=0,4&mcustomize=lawnew\\_view.jsp&dataserno=201807160001](https://www.sfb.gov.tw/en/home.jsp?id=100&parentpath=0,4&mcustomize=lawnew_view.jsp&dataserno=201807160001)

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- (iii) The press release published by the Taipei Exchange ('TPEX') on 4 June 2020, which advised that it had imposed a penalty on Medigen for failing to follow the TPEX procedures for verification and disclosure of material information.<sup>7</sup>
- (iv) Medigen's announcement on TPEX regarding a media article on 19 February 2020 about Mr Bill Ou, Medigen's chief financial officer and executive director, and also a director of TBG Xiamen (appointed by TBG Inc).
- P. TDL's announcement titled 'CE Mark Approval of SARS-CoV-2 Antigen Rapid Test' which was released on MAP on 11 November 2020 and disclosed that TBG Xiamen had received CE Mark approval for its SARS-CoV-2 Antigen Rapid Test on 30 October 2020.
- Q. Listing Rule 3.1, which requires a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.
- R. Listing Rule 3.19A.2 which requires an entity to tell ASX the following:
- 'A change to a notifiable interest of a director of the entity (or in the case of a trust, a director of the responsible entity of the trust) including whether the change occurred during a closed period where prior written clearance was required and, if so, whether prior written clearance was provided. The entity must complete Appendix 3Y and give it to ASX no more than 5 business days after the change occurs.'*
- S. Listing Rule 3.19B which states that:
- 'An entity must make such arrangements as are necessary with a director of the entity (or in the case of a trust, a director of the responsible entity of the trust) to ensure that the director discloses to the entity all the information required by the entity to give ASX completed Appendices 3X, 3Y and 3Z within the time period allowed by listing rule 3.19.A. The entity must enforce the arrangements with the director.'*
- T. Listing Rule 10.1 which provides:
- 'An entity ... must ensure that neither it, nor any of its child entities, acquires a substantial asset from, or disposes of a substantial asset to, any of the following persons without the approval of holders of the entity's ordinary securities.'*
- 10.1.1 *A related party of the entity.*
- 10.1.2 *A child entity of the entity.*
- 10.1.3 *A person who is, or was at any time in the 6 months before the transaction or agreement, a substantial (10%+) holder in the entity.*
- 10.1.4 *An associate of a person referred to in rules 10.1.1 to 10.1.3.*
- 10.1.5 *A person whose relationship to the entity or a person referred to in rules 10.1.1 to 10.1.4 is such that, in ASX's opinion, the transaction should be approved by security holders.'*
- U. Listing Rule 10.2 which states:
- 'An asset is substantial if its value or the value of the consideration being paid or received by the entity for it is, or in ASX's opinion is, 5% or more of the equity interests of the entity, as set out in the latest accounts given to ASX under the listing rules.'*

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<sup>7</sup> Available at: [https://www.tpex.org.tw/web/about/news/news/news\\_detail.php?l=en-us&doc\\_id=9450](https://www.tpex.org.tw/web/about/news/news/news_detail.php?l=en-us&doc_id=9450)

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- 10.2.1 *In determining whether an asset meets the threshold in rule 10.2 to be a substantial asset: ...*
- *separate acquisitions or disposals will be aggregated if, in ASX's opinion, they form part of the same commercial transaction.*
- V. Section 5.4 of *Guidance Note 24: Acquisitions and disposals of substantial assets involving persons in a position of influence* which includes the following statements:
- 'Listing Rule 10.1 does not apply to an acquisition or disposal under an agreement to acquire or dispose of a substantial asset. The exception is only available if the entity entered into the agreement:*
- (a) before it was listed and it disclosed the existence and material terms of the agreement in the prospectus, PDS or information memorandum lodged with ASX under Listing Rule 1.1 condition 3; or*
  - (b) after it was listed and it complied with the Listing Rules when it did so.'*
- W. Listing Rule 12.2 which provides:
- 'An entity's financial condition (including operating results) must, in ASX's opinion, be adequate to warrant the continued quotation of its securities and its continued listing.'*
- X. Listing Rule 12.5 which provides:
- 'An entity's structure and operations must be appropriate for a listed entity.'*

### Questions and Request for Information

Having regard to the above, ASX asks TDL to respond separately to each of the following questions and requests for information:

#### *Director's Interest Notice*

1. ASX notes that:
  - Section 10E(ii) of the Annual Report disclosed that Dr Chang held a balance of 500,000 Shares at 1 January 2019, disposed of 500,000 Shares during FY2019 ('Disposal') and, in turn, held no Shares at 31 December 2019.
  - It appears that no Appendix 3Y was lodged in relation to the Disposal (noting that the last Appendix 3Y for Dr Chang was lodged on 5 May 2016).

Consequently, it appears that TDL may have breached Listing Rules 3.19A and/or 3.19B.

In light of the above and having regard to Listing Rules 3.19A.2 and 3.19B and *Guidance Note 22: Director Disclosure of Interests and Transactions in Securities - Obligations of Listed Entities*:

- a) Please provide full details of the Disposal.
- b) Please explain why an Appendix 3Y was not lodged in relation to the Disposal.
- c) What arrangements does TDL have in place under Listing Rule 3.19B with its directors to ensure that it is able to meet its disclosure obligations under Listing Rule 3.19A?
- d) If the current arrangements are inadequate or not being enforced, what additional steps does TDL intend to take to ensure compliance with Listing Rule 3.19B?

## Medigen

2. ASX notes the following in relation to the 2015 Distribution Agreement:

- Medigen has been the controlling shareholder (51.76% shareholding) and ultimate parent company of TDL since 29 January 2016.
- Medigen has been a party to whom Listing Rule 10.1 applies since 22 May 2013.<sup>8</sup>
- It appears to be an agreement to sell goods to a Listing Rule 10.1 party over an extended term which constitutes a disposal of those goods to a Listing Rule 10.1 party for the purposes of Listing Rule 10.1 (see section 6.5 of Guidance Note 24 in relation to term contracts).
- It was executed in January 2015.
- It does not appear to have been disclosed in the Prospectus or in the Notice.
- The Investor Presentation did not disclose that Medigen was one of TBG's distributors or customers.
- Since 1 July 2016, TBG Taiwan has made sales of goods to Medigen totalling \$4,197,747, as set out in the table below. In aggregate, these sales have exceeded 5% of TDL's equity interests at 30 June 2016 (and in each reporting period thereafter). Furthermore, sales of goods to Medigen in both FY2017 and FY2018 exceeded 5% of TDL's equity interests in those respective years.

\$	2H FY2016*	FY2017	FY2018	FY2019	1H FY20	Total
Sale of goods to Medigen <sup>#</sup>	584,019	1,815,907	954,586	448,616	394,619	<b>4,197,747</b>
TDL's sales revenue	1,183,095	3,505,273	2,848,954	3,066,839	1,787,415	<b>12,391,576</b>
% of TDL's sales revenue	49%	52%	34%	15%	22%	34%
5% of TDL's equity interests**	1,049,409	749,687	592,457	642,818	456,571	

<sup>#</sup> From related party transaction disclosures in TDL's financial statements.

\* 1 July 2016 - 31 December 2016

\*\* Calculated based on TDL's equity interests at the end of the relevant reporting period. At 30 June 2016 (the end of the first reporting period following the 2016 Reinstatement), 5% of TDL's equity interests amounted to \$1,159,383.

Based on the information above, it appears that TDL may have breached Listing Rule 10.1 in relation to the 2015 Distribution Agreement.

In light of the above:

- a) Please explain why the Company did not disclose the 2015 Distribution Agreement in the Prospectus or in the Notice.
- b) Has TDL considered the application of Listing Rule 10.1 to the 2015 Distribution Agreement? If the answer to this question is 'no', why not?
- c) Please detail the material terms of the 2015 Distribution Agreement, and specifically note whether it includes a net profit sharing arrangement akin to the 2020 Distribution Agreement.

3. ASX notes the following in relation to the 2015 Distribution Agreement:

- It was entered into on 15 February 2020 and provides that Medigen is the worldwide exclusive distributor of TBG Taiwan's SARS-CoV-2 test kits (except in Australia and New Zealand).

<sup>8</sup> Medigen's shareholding in the Company increased from 8.48% to 19.61% on 22 May 2013 and, in turn, Medigen became a party to whom Listing Rule 10.1.3 applies. In addition, Listing Rule 10.1.1 has applied to Medigen since 29 January 2016.

- Medigen is party to whom Listing Rule 10.1 applies by virtue of Listing Rules 10.1.1 and 10.1.3.
- It appears to be an agreement to sell goods to a Listing Rule 10.1 party over an extended term which constitutes a disposal of those goods to a Listing Rule 10.1 party for the purposes of Listing Rule 10.1.
- Based on the Activities Report, TBG Taiwan made sales of goods to Medigen under the 2020 Distribution Agreement of \$270,725 in the period from 15 February 2020 to 30 September 2020.

Given the sales to 30 September 2020 equate to 2.1% of TDL's equity interests at 31 December 2019 and the 2020 Distribution Agreement expires on 14 February 2023, it appears likely that total sales over the term of the 2020 Distribution Agreement will exceed 5% of TDL's equity interests.

Furthermore, TBG Taiwan received 'advance receipts' from Medigen amounting to \$1,107,717 in 1H FY20, which equate to 8.6% of TDL's equity interests at 31 December 2019.

Based on the information above, it appears that TDL may have breached Listing Rule 10.1 in relation to the 2020 Distribution Agreement.

In light of the above:

- Did TDL consider the application of Listing Rule 10.1 to the 2020 Distribution Agreement? If the answer to this question is 'no', why not?
- Please provide a copy of the minutes of the meetings of the directors of TBG Taiwan and TDL approving the 2020 Distribution Agreement (not for release to the market).<sup>9</sup>
- Please list the directors of TBG Taiwan and specify whether they are employed or engaged by TDL or by Medigen.

4. ASX notes that:

- TDL disclosed related party expenses pertaining to an office lease in its financial statements for FY2016 and FY2017.<sup>10</sup>
- The lease agreement provided in response to question 2(i) of the March Query Letter commenced on 1 January 2018 and concluded on 31 December 2020.

In light of the above:

- Please provide a copy of the lease agreement which was in place with Medigen between the 2016 Reinstatement and 31 December 2017 (not for release to the market).
- Has the office lease been extended beyond 31 December 2020? If the answer to this question is 'yes', please provide a copy of the agreement (not for release to the market).

5. Please provide an account of TDL's understanding of the circumstances which gave rise to:

- The Taiwan Securities and Futures Bureau imposing an administrative fine on Medigen in relation to TDL's internal procedures governing acquisitions and disposals of assets (see sub-paragraph O(ii) above).

<sup>9</sup> The fact that ASX tells an entity that a document is not for release to the market does not prevent ASX from releasing any of the information contained in the document (as opposed to the document itself) to the market if ASX considers it necessary to inform the market.

<sup>10</sup> \$85,421 in FY2016 and \$175,190 in FY2017.



- b) TPEX imposing a penalty on Medigen on 4 June 2020 for failing to follow the TPEX procedures for verification and disclosure of material information (see sub-paragraph O(iii) above).
6. To TDL's knowledge, has Medigen (including its subsidiaries and associates and/or any of its officers) been the subject of any regulatory investigation, review, audit, assessment or action in Taiwan or mainland China that is not identified in paragraph O above?
7. ASX notes that:
- Medigen is listed on TPEX.
  - Medigen's annual reports and financial statements for FY2018 and FY2019 ('Medigen Reports') are not currently available on Medigen's website.<sup>11</sup>

In light of the above, please provide a copy of the following:

- a) the Medigen Reports; and
- b) any announcements made by Medigen since 1 January 2018 which reference TDL (including its subsidiaries or associates).

*TBG Xiamen (TDL's interest - 48.23%)*

8. ASX notes that TBG Taiwan has made sales to and purchases of goods and fixed assets from TBG Xiamen, as set out in the table below.

\$	FY2019	1H FY20	Total
Sale of goods to TBG Xiamen	866,436	382,233	<b>1,248,669</b>
TDL's sales revenue	3,066,839	1,787,415	<b>4,854,254</b>
% of TDL's sales revenue	28%	21%	<b>26%</b>
Purchase of goods from TBG Xiamen*	-	1,157,411	
Purchase of fixed assets from TBG Xiamen	-	135,738	

Source: Related party transaction disclosures in TDL's financial statements. TBG Xiamen has been accounted for as an associate since 3 May 2019.

\*At 30 June 2020, \$692,337 was payable to TBG Xiamen and \$585,281 had been advanced to TBG Xiamen.

In light of the above, which products did TBG Taiwan:

- a) sell to TBG Xiamen in FY2019 and 1H FY20?
- b) purchase from TBG Xiamen in 1H FY20?
9. ASX notes that TBG Xiamen has owed a material sum of money to TDL since 30 June 2019 and that an impairment provision has been recognised against the receivables, as set out in the table below.

\$	30 June 2019	31 December 2019	30 June 2020
Trade receivables	983,200	1,413,876	1,401,430
Other receivables	442,302	447,164	466,789
<b>Total receivables</b>	<b>1,425,502</b>	<b>1,861,040</b>	<b>1,868,219</b>
Impairment provision	-	1,861,040	1,143,848
% of TBG Xiamen receivables	-	100%	61%

Source: Related party transaction disclosures in TDL's financial statements.

<sup>11</sup> See webpage at <https://www.medigen.com.tw/en/category/financial-statement/>



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In light of the above, please explain why an impairment provision has been recognised against the amounts owing to TBG Taiwan from TBG Xiamen.

10. How much revenue has TBG Xiamen derived from the sale of SARS-CoV-2 test kits to date? Please include a breakdown of sales to customers in mainland China and export sales.
11. ASX notes that:
- TBG Taiwan and TBG Xiamen have separate CE mark authorisations for SARS-CoV-2 nucleic acid test kits.
  - TBG Taiwan has CE mark authorisation for its SARS-CoV-2 IgG/IgM antibody rapid test kit.
  - TBG Xiamen has CE mark authorisation for its SARS-CoV-2 antigen rapid test.
  - TBG Inc has responsibility for overseeing and managing TBG Xiamen's research and development and product manufacture (see sub-paragraph J(i) above).

In light of the above:

- a) Please clarify the differences (if any) between the two SARS-CoV-2 nucleic acid test kits.
  - b) Did TBG Inc/TBG Taiwan develop the SARS-CoV-2 nucleic acid and antigen rapid test kits for TBG Xiamen?
  - c) What sales protocols and procedures (if any) have been established between TBG Taiwan and TBG Xiamen regarding the sales and export of the abovementioned SARS-CoV-2 test kits into territories such as Europe?
12. Does Medigen have any distribution arrangements in place with TBG Xiamen (or any of its subsidiaries)? If the answer to this question is 'yes', please provide a copy of the agreement (not for release to the market) and detail the material terms of the agreement.
13. Is the licensing agreement between TBG Taiwan and TBG Xiamen still on foot (see sub-paragraph J(ii) above)?
14. Who are TBG Xiamen's three supervisors (see sub-paragraph J(i) above)?
15. Please provide a copy of the external valuation report for TBG Xiamen (see sub-paragraph K(v) above) (not for release to the market).

#### *Customers and other arrangements*

16. Please identify:
- a) the regular customers (other than Medigen and TBG Xiamen) referred to in sub-paragraphs I(ii) and K(vi) above; and
  - b) the 'major sales distributor' referred to in sub-paragraph I(i) above.
17. Please provide details of the collaboration arrangements and product licensing agreements that TDL entered into with external parties in FY2019 (see sub-paragraph K(i) above).

#### *Other*

18. Please confirm that TDL is complying with the Listing Rules and, in particular, Listing Rule 3.1.

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19. Please confirm that TDL's responses to the above questions and requests have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of TDL with delegated authority from the board to respond to ASX on disclosure matters.

**When and where to send your response**

This request is made under Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **9:30am AEDT on Wednesday, 3 February 2021**.

ASX reserves the right to release a copy of this letter and your response on the ASX Market Announcements Platform under Listing Rule 18.7A. Accordingly, your response should be in a form suitable for release to the market.

Your response should be sent to me by e-mail. It should not be sent directly to the ASX Market Announcements Office. This is to allow me to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

Please also note that once ASX has received and analysed the information above, it is possible that ASX will need to make further enquiries of TDL.

**Listing Rules 3.1 and 3.1A**

In responding to this letter, you should have regard to TDL's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. It should be noted that TDL's obligation to disclose information under Listing Rule 3.1 is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

**Release of correspondence with ASX**

ASX reserves the right to release a copy of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A.

**Enquiries**

If you have any queries or concerns about any of the above, please contact me.

Yours sincerely

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**Corey Lian**  
Adviser, Listings Compliance (Sydney)