

19 July 2020

Melissa Kostopoulos
Compliance Adviser
ASX, Melbourne

Dear Melissa,

Genetic Technologies Limited (**GTG** or **Company**) acknowledge receipt of the ASX letter of 17 July 2020 at 5.22pm (**Query Letter**).

In response to the particular information requests in the Query Letter, using the same numbering, GTG responds that –

1. When was the video referred to in paragraph D above published?

The video is stated in its link as first published on **12 June 2020** - noting that GTG first disclosed to the ASX market its proposed use of funds for development of a COVID-19 severity test on **29 May 2020** in its prospectus lodged that day with the ASX.

On page 10 of that prospectus on 29 May 2020 the statement was included - "*We intend to use the net proceeds of this offering to support the introduction and distribution of our new*

*products in the United States, for general product research and development, including the development of polygenic risk tests, and reimbursement studies with TGen in the United States, for implementation of our consumer initiated testing platform, **preparation for potential COVID-19 testing, COVID-19 risk test for developing serious disease from contracting COVID-19, for working capital and new equipment purchases. See "Use of Proceeds."***

2. Has GTG previously announced to the market that:

a) The cost of developing the Test would be somewhere between US\$1.0 million and US\$1.5 million?

Individual comments referred to in the video may not in and of themselves be considered to be material on their own, however reference to our re-occurring R&D spend and product development costs are contained in our Annual reports and 4C Updates to the market.

Further we note that under GTG's prospectus lodged with the ASX on **29 May 2020** GTG raised US\$8 million and included disclosure in the use of funds in that prospectus that the funds raised would be utilised for working capital and the cost of development of the COVID-19 severity risk test.

The comment by Dr Muchnicki referred to the general cost of developing polygenic risk score tests as ranging between US\$1m and US\$1.5m. The Covid-19 Risk Severity test is anticipated to come within this range as much of the cost of development comes from the use of existing GTG staff and internal resources, facilities and equipment at GTG's existing laboratory.

It is important to note that development of a risk assessment test is very different from the timeline and cost of development of a new therapeutic product or a new medical device. Typically for new therapeutic drugs the timeline is many years - but a risk assessment test as an Laboratory Derived Test (LDT) does not have the same regulatory requirements.

We also note that the statement in the video only refers to the development timeline / cost for the test - it does not take into account any additional clinical trial validation (which GTG may but is not obliged to undertake), LDT registration for the particular laboratory, production / manufacturing, distribution, sales and marketing activities. Market take up of such predicative tests / establishing distribution channels can involve significant costs and time - for example educating key opinion leaders on the application of the predicative test. This is not included in the development estimate above.

b) The timeframe to develop the Test is 3 to 6 months?

The Company in an announcement lodged on the ASX announcements platform that on **27 May 2020** included a statement referring to the “*rapid development*” of the COVID-19 severity test, however the ASX requested this statement and any reference to the test be removed from the announcement.

The reference to 3 to 6 months in the video was a general statement in the context of GTG's existing capabilities to develop tests around within that period and of itself would not be unusual taking into account this is an additional LDT test leveraging off GTG's existing NATA / CLIA certification and its existing experience reflected in its pipeline and capabilities.

GTG is actually in a position to have the test released into the US market as a laboratory developed test (**LDT**) within 45 days from completion of the cross validation studies which are dependent on access to additional COVID-19 Patient sequenced DNA. Based on GTG's existing regulatory approved CLIA and NATA registered laboratory, GTG anticipates the registration of an LDT COVID-19 severity test should take less than 45 days after that validation (based on estimates received). A time frame of 3-6 months is a reasonable estimate subject to access to the appropriate resources and access to the DNA data from bio banks for cross validation.

However, the development timeframe is not material to an investor - the real question is how long would it take for such an LDT test to be NATA accredited for the individual laboratory to offer the test commercially to the public. The actual time for a COVID-19 severity test to be able to be made commercially available to the public by a laboratory is subject to a large number of factors and GTG has not provided any public guarantee as to when commercial sales could be achieved. This will depend on the access to DNA data for sequenced COVID-19 positive patients for cross validation by GTG and then healthcare regulatory review for the laboratory LDT.

The Company currently has a number of other tests in different stages of development. The time for development for the COVID-19 risk test will be directly influenced by the results of the initial Genome Wide Association Study (“**GWAS**”) and statistical analysis of test performance along with staff allocations and access to genotype data and clinical risk factors.



Access to data for sequenced COVID-19 positive patients for cross validation is the single biggest determinant to date.

c) GTG's sales of its GeneType for Breast Cancer and GeneType for Colorectal Cancer tests (as at late June 2020) have been adversely impacted by the inability of consumers to visit medical practitioners?

Please refer to the following:

- ASX release dated **1 April 2020** which states

"In light of world-wide recommendations on social distancing, which is impacting on our ability to fully engage with physicians, we have brought forward our plans to introduce a Consumer Initiated Testing (CIT) Platform."

- ASX release on **17 April 2020** which states:

"in light of world-wide recommendations on social distancing, which is impacting on our ability to fully engage with physicians, we have brought forward our plans to introduce a Consumer Initiated Testing (CIT) Platform."

- ASX release on **30 April 2020** see reference to *"early sales halted by pandemic"*
- Page 5 of the F1 prospectus released to the ASX market on **13 May 2020** which states:

"The COVID-19 pandemic is having a negative impact on global markets and business activity, which has had an effect on the operations of the Company, including but not limited to, that sales of our products have been impacted not only by the inability for consumers to visit their practitioners but also the difficulty our sales team is having in arranging face to face meetings with practitioners. Our sales team has found it very difficult to reach practitioners to build on the sales momentum created prior to the pandemic, thus, sales have effectively ceased for the short term."

d) Clinics have stopped taking samples for GeneType for Breast Cancer and GeneType for Colorectal Cancer tests as a result of Covid-19?

See references set out in response to question 2C above.

If the answer to any of a) - d) above is 'yes', please provide details of the relevant announcement(s).

If the answer to any of a) - d) above is 'no', please explain why the relevant information was not released to the market, commenting specifically on when you believe GTG was obliged to release the relevant information under Listing Rules 3.1 and 3.1A.

Individual comments referred to in response to questions (2) a & b above were not in and of themselves considered to be material on their own - however reference to each of them has been made in various ASX announcements as referred to above.

3. Please clarify whether GTG is proceeding to complete development of the Test based on data from 1,500 Covid-19 patients (see sub-paragraphs C(iii) and E(i) above), and whether this data is sourced from samples of approximately 3,000 patients (see sub-paragraph F(i) above) or approximately 6,000 patients (see subparagraphs D(iv) and E(i) above).

The number of samples required is influenced by a series of complex factors which vary during the development of the test. Furthermore, since the Covid-19 pandemic is a current and active health emergency, the numbers of patients and the data available from bio banks is continuously varying.

Notwithstanding those comments we confirm that:

- GTG's prototype test was developed on approximately the data obtained from 6,000 patients however upon further analysis it became evident that only 1500 patients from that sample satisfied the polygenic risk testing criteria.
- The mention of numbers of samples therefore refers to both the gross (6,000) and net figures (3,000). Gross being the entire population and net being those that fit within the stringent requirements for suitability.
- For example certain samples may have been double counted due to multiple hospitalisations by the same person/s etc.

We note that sub-paragraph D(iv) relates to examples of sample numbers that we have used in the past for test development. However, these numbers are not absolute and we have developed tests on smaller numbers. Statistical evaluation of the COVID-19 severity test has been one of the best in all of our past tests developed, which has resulted in a reduced number of samples being required

4. Will the Test require approval or authorisation from: a) the Food and Drug Administration (FDA) in the United States?

No - as a laboratory developed test (LDT), however the Company may elect to apply for FDA approval under the US COVID-19 fast track regulations - as this would enable a more rapid release of the product across a number of suitable third party laboratories in the United States (as opposed to CLIA requirements imposed on each individual laboratory).

b) the Therapeutic Goods Administration (TGA) in Australia?

No - initially GTG is utilising its existing laboratory NATA accreditation and will also focus on the US market via its CLIA accreditation enabling rapid access to the USA market.

5. When does GTG expect to submit:

a) its complete technical package to the Centres for Medicare and Medicaid Services (CMS) for review and approval (see sub-paragraph F(vi) above)?

CLIA has notified GTG in writing that review and approval should be completed within 45 days from receipt of final samples for cross validation - but as mentioned this depends on receipt of the data samples from bio banks for such cross validation which is hoped will occur in the next 30 days.



b) its technical file to Clinical Laboratory Improvement Amendments (CLIA) for approval (see subparagraph F(vi) above)?

See a) above as CLIA and CMS are synonymous.

c) its final independent data set for test validation to the National Association of Testing Authorities (NATA) for assessment (see sub-paragraph F(vi) above)?

Upon receipt of additional data from biobanks, hospitals or laboratories expected within 30 days.

6. How many SNP array panels have been ordered from Thermo Fisher Scientific, and how much did they cost (see sub-paragraph F(iii) above)?

Sufficient arrays to test 1000 samples have been ordered from Thermo Fisher Scientific - the cost is commercially sensitive, but it is within the outline of development costs referred to above.

We stress that this is for product development / testing - not for commercial sales, however we have a high level of confidence that such arrays will be reordered in the same form based on their complex SNP'S combinations for commercial rollout post laboratory validation.

7. Is the Test designed to be administered by medical and healthcare professionals?

As with our current tests a health care professional will be required to provide the results and approve the request to be tested which will be streamlined on our Customer Initiated Testing ("CIT") platform. A direct to consumer ("DTC") approach may require FDA/TGA approvals however this will be finalised upon completion of regulatory review.

8. What would approval from CLIA in the United States and accreditation from NATA in Australia facilitate in terms of the provision of the Test?

CLIA and NATA Approvals will allow for GTG to offer the LDT tests for commercial sale.

9. Please provide a copy of GTG's correspondence with the following parties (not for release to the market)

1: a) Major manufacturers (including Thermo Fisher Scientific) confirming capacity to scale up production of the Test (see sub-paragraph F(iv) above).

There were significant numbers of communications via zoom, by phone and email with parties in Australia and the USA (including the CEO of Thermo Fisher Australia and also Illumina personell). We have been an existing client of both groups for over 10 years for the provision of reagents and customised SNP arrays. A sample of the email communications is attached.

b) Several international biobanks and clinical laboratories in relation to the sourcing of an independent cross-validation dataset (see sub-paragraph F(ii) above).



Over 30 international biobanks, hospitals and clinical laboratories have been contacted in relation to cross-validation datasets. For example see supporting GTG email documents attached. The Company has received a significant number of responses from international biobanks, hospitals and clinical laboratories and is in discussions with 6 of the organisations contacted to obtain access to data.

c) CMS, CLIA and NATA (see sub-paragraph F(vi) above).

- Medical Technologist/MLS Regulatory Compliance Lead for the Centers for Medicare and Medicaid Services (CMS), Survey and Certification Group/Division of Laboratory Services
- Client Coordinator at National Association of Testing Authorities, Australia (NATA)

10. How many GeneType for Breast Cancer tests and GeneType for Colorectal Cancer tests has GTG sold to date, and how much revenue has been derived from those sales?

Approximately 14,000 tests with over \$10m in revenue since inception in 2012. This revenue is from delivered orders and has been reflected in revenues reported in the Company's financial statements since 2012. In the June 2020 half year the Company has sold approximately 150 tests and generated approximately \$5,000 in revenue (not audited), the majority of tests have been provided free of charge for practitioner validation and Australian market entry purposes.

11. Has GTG's genetic testing laboratory been utilised as a high-throughput Covid-19 testing laboratory (see sub-paragraph B(i) above)? If the answer to this question is 'yes'. How many tests has GTG processed to date, and how much revenue has GTG derived from the provision of this service?

No - Existing Victorian pathology providers have been able to process current testing demand.

12. ASX notes that GTG appears to have the in-house capacity to produce or conduct between 250,000 and 360,000 tests per annum (see sub-paragraphs B(iii) and F(v) above). Please confirm how GTG currently intends to allocate its in-house capacity between producing the GeneType for Breast Cancer test, the GeneType for Colorectal Cancer test, and the Test, and conducting Covid-19 testing for the Australian government.

After initial discussions with other commercial laboratories there have been no requests made to GTG, nor formal agreements entered into to make the transition to inhouse COVID-19 testing, therefore it currently poses no restriction on our internal capabilities and we have made no assurances that such capability will be available if and when it may be requested.

Given the uniqueness of the GENETYPE COVID-19 Severity risk test we believe our laboratory capabilities will be much more useful for our PRS testing.

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



GTG believes that it has already disclosed to the ASX and NASDAQ markets its intention to develop and commercialise a COVID-19 severity test - this has been released to the ASX market on a number of occasions.

GTG submits that much of the information sought in the ASX Query Letter relates to product development / market soundings activity commonly undertaken by any company in any development / commercialisation and proposed launch of a new product. GTG has undertaken pre-marketing activities in the US (the largest healthcare market globally) - and GTG submits those pre-marketing activities of themselves are not material for disclosure to the ASX Announcements platform under ASX Listing Rule 3.1.

GTG also submits the ASX market is generally aware of GTG's development plans for a COVID-19 severity test - it is within GTG's core business activity being an additional Polygenic Risk Score test ("PRS") for risk of Hospitalisation from an Infectious Disease. The cost and timing of that development of a COVID-19 test will be similar to GTG's development activities for other polygenic risk assessment tests. As mentioned this is part of GTG's core business activity - reflected in GTG's registered "*GeneType for Breast Cancer*" test (for risk assessment for breast cancer) and also GTG's on-going portfolio of other risk assessment tests (for example in risk assessment for Colon cancer with GTG's "*GeneType for Colorectal Cancer*").

Obviously public interest (particularly in the US) and global health regulators is generating a desire to accelerate COVID-19 products and this is well known to markets and GTG is responding to that public and regulatory interest and community need.

The Company confirms it is in compliance with the ASX Listing Rules, in particular Listing Rule 3.1.

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

Confirmed.

Yours sincerely

Dr George Muchnicki Acting CEO and Justyn Stedwell Company Secretary
On behalf of the Board of Directors
Genetic Technologies Limited

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17 July 2020

Reference: 20557

Mr Justyn Stedwell
Company Secretary
Genetic Technologies Limited
60-66 Hanover Street
Fitzroy Victoria 3065

By email: justyn@stedwell.com.au

Dear Mr Stedwell

Genetic Technologies Limited ('GTG'): Query letter

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

- A. GTG's announcement titled 'Market update on sales, early test results and launch of CIT' released on the ASX Market Announcements Platform ('MAP') on 1 April 2020, which disclosed the following:
 - (i) *'As announced to the market on 31 January 2020, the Company has fully commissioned its Australian Laboratory for the provisioning of its generation 3 breast cancer test (GeneType for Breast Cancer), with sales having commenced during the quarter. We are pleased to report that this is now accompanied by the first-to-market GeneType for Colorectal Cancer test with sales also having now commenced.'*
 - (ii) *'Both tests have been well received by medical practitioners, with over 15 clinics in Australia having agreed to offer the GeneType portfolio of tests. Overall, in excess of 100 test kits having been requested and approximately half of those samples have been received into the Melbourne laboratory during the first 4 weeks on market.'*
- B. GTG's announcement titled 'Covid-19 testing capacity at GTG Accredited Laboratory' released on MAP on 17 April 2020, which disclosed the following (emphasis added):
 - (i) [GTG] *'has developed a detailed implementation plan to enable a temporary transition of our genetic testing laboratory to a high-throughput Covid-19 testing laboratory, should it be required by Government agencies to assist with demand.'*
 - (ii) *'GTG has a fully NATA and CLIA accredited laboratory which places it in a unique position to service both the Australian and the USA markets subject to regulatory approvals.'*
 - (iii) *'Utilising current equipment GTG already owns and is in operation we are in a position to conduct approximately 360,000 tests per annum with the potential to double output as required.'*
- C. GTG's announcement titled 'US Patent Office Grants Key Risk Test Patent' released on MAP on 19 June 2020 ('19 June Announcement'), which disclosed the following (emphasis added):
 - (i) GTG had been granted the patent titled 'Methods for assessing risk of developing breast cancer' in the United States relating to its polygenic risk test for breast cancer.
 - (ii) GTG had filed a provisional patent for its COVID-19 Severity Risk Test ('Test') titled '2020901739 – Methods of assessing risk developing a severe response to Coronavirus infection'.
 - (iii) *'... the Company has commenced analysis of the early, available genomic and phenotypic data from 1,500 COVID-19 patients ... and developed a prototype predictive model to identify those patients most likely to require hospitalisation, should they contract COVID-19.'*

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- (iv) *'GTG believes that this product, once developed and subject to any regulatory approvals, may be effectively applied to manage a safe return to work in areas with high infection rates and help communities understand risk stratification to prioritise access to vaccines to those most vulnerable and susceptible to complications should they contract COVID-19.'*

ASX notes that the 19 June Announcement was the subject of an ASX query letter dated 29 June 2020 relating to GTG's compliance with Listing Rules 3.1 and 15.7 which was released on MAP, together with GTG's response, on 3 July 2020.

- D. An interview between Mr Dave Gentry, CEO of RedChip Companies, and Dr George Muchnicki, GTG's Acting CEO, titled 'Genetic Technologies: Developing New COVID-19 Risk Assessment Test' (available at <https://www.youtube.com/watch?v=M-0NSeUuawc>), which disclosed the following information:
- (i) The cost of developing the Test would be somewhere between US\$1.0 million and US\$1.5 million.
 - (ii) GTG has a team of 6 people working on developing the Test in Melbourne.
 - (iii) The timeframe to develop the Test is 3 to 6 months.
 - (iv) *'We usually require 3,000 to 6,000 samples before we have a reasonable amount of data to give us confidence in presenting this type of test to the community.'*

ASX notes that RedChip Companies is GTG's Investor Relations and Media contact in the United States.

- E. A webinar interview between Mr Dave Gentry and Dr George Muchnicki published on 24 June 2020 (available on the webpage https://www.redchip.com/events/63/Gene-Tech_Bio_Webinar/gene), which disclosed the following information:
- (i) GTG has studied 6,000 data points from Covid-19 patients of which 1,500 samples were relevant for the Test.
 - (ii) Sales of the GeneType for Breast Cancer and GeneType for Colorectal Cancer tests have been impacted due to the inability of consumers to visit their practitioners.
 - (iii) Clinics have stopped taking samples for GeneType for Breast Cancer and GeneType for Colorectal Cancer tests as a result of Covid-19, but GTG hopes they will restart soon.
- F. GTG's media release titled 'Genetic Technologies Provides Update on COVID-19 Disease Severity Test' ('Press Release') dated 15 July 2020 published on GlobeNewswire at approximately 10pm AEST (8am US ET) (available at <https://www.globenewswire.com/news-release/2020/07/15/2062531/0/en/Genetic-Technologies-Provides-Update-on-COVID-19-Disease-Severity-Test.html>), which disclosed the following information:
- (i) *'First successful working prototype developed on a data sample of approximately 3,000 patients'*
 - (ii) *'The Company is in discussions with several international biobanks and clinical laboratories to source an independent cross-validation dataset'*
 - (iii) *'Genetic Technologies has commenced ordering its first SNP [Single Nucleotide Polymorphis] array panel from US-based Thermo Fisher Scientific ...'*
 - (iv) *'Genetic Technologies has confirmed capacity to scale up production for a global-roll out of the COVID-19 Severity Risk Test (reagent and SNP array panel) with major manufacturers, including Thermo Fisher Scientific.'*
 - (v) *'Genetic Technologies' Australian facilities will have the capacity of producing up to 250,000 tests per year.'*

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- (vi) *'Discussions held with Centres for Medicare and Medicaid Services (CMS) and National Association of testing Authorities, Australia ("NATA") for regulatory Approval for the COVID-19 Severity Risk Test in the United States and Australia*
- *A complete technical package will be submitted to the Centres for Medicare and Medicaid Services (CMS) for review and approval*
 - *Clinical Laboratory Improvement Amendments (CLIA) turn-around time for approval expected to be approximately 45 days from submission ...*
 - *NATA assessment to be provided upon internal review of final independent data set for test validation'*
- G. The change in the price of GTG's securities from a closing price of \$0.005 on Wednesday (15 July 2020) to a high of \$0.013 yesterday morning (16 July 2020), together with the very significant increase in the volume of GTG's securities traded yesterday morning, prior to the pause in trading imposed by ASX at 10:27am AEST and the subsequent trading halt.
- H. 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.
- I. The definition of 'aware' in Chapter 19 of the Listing Rules, which states that:
- 'an entity becomes aware of information if, and as soon as, an officer of the entity (or, in the case of a trust, an officer of the responsible entity) has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity' and section 4.4 in Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B "When does an entity become aware of information.'*
- J. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure, provided that each of the following are satisfied.
- '3.1A Listing rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:*
- 3.1A.1 One or more of the following applies:*
- *It would be a breach of a law to disclose the information;*
 - *The information concerns an incomplete proposal or negotiation;*
 - *The information comprises matters of supposition or is insufficiently definite to warrant disclosure;*
 - *The information is generated for the internal management purposes of the entity; or*
 - *The information is a trade secret; and*
- 3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and*
- 3.1A.3 A reasonable person would not expect the information to be disclosed.'*

Questions and Request for information

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

1. When was the video referred to in paragraph D above published?

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2. Has GTG previously announced to the market that:
- a) The cost of developing the Test would be somewhere between US\$1.0 million and US\$1.5 million?
 - b) The timeframe to develop the Test is 3 to 6 months?
 - c) GTG's sales of its GeneType for Breast Cancer and GeneType for Colorectal Cancer tests (as at late June 2020) have been adversely impacted by the inability of consumers to visit medical practitioners?
 - d) Clinics have stopped taking samples for GeneType for Breast Cancer and GeneType for Colorectal Cancer tests as a result of Covid-19?
- If the answer to any of a) - d) above is 'yes', please provide details of the relevant announcement(s).
- If the answer to any of a) - d) above is 'no', please explain why the relevant information was not released to the market, commenting specifically on when you believe GTG was obliged to release the relevant information under Listing Rules 3.1 and 3.1A.
3. Please clarify whether GTG is proceeding to complete development of the Test based on data from 1,500 Covid-19 patients (see sub-paragraphs C(iii) and E(i) above), and whether this data is sourced from samples of approximately 3,000 patients (see sub-paragraph F(i) above) or approximately 6,000 patients (see sub-paragraphs D(iv) and E(i) above).
4. Will the Test require approval or authorisation from:
- a) the Food and Drug Administration (FDA) in the United States?
 - b) the Therapeutic Goods Administration (TGA) in Australia?
- If the answer to either a) or b) above is 'yes', please provide details of the requisite approvals or authorisations and the anticipated timeframes.
5. When does GTG expect to submit:
- a) its complete technical package to the Centres for Medicare and Medicaid Services (CMS) for review and approval (see sub-paragraph F(vi) above)?
 - b) its technical file to Clinical Laboratory Improvement Amendments (CLIA) for approval (see sub-paragraph F(vi) above)?
 - c) its final independent data set for test validation to the National Association of Testing Authorities (NATA) for assessment (see sub-paragraph F(vi) above)?
6. How many SNP array panels have been ordered from Thermo Fisher Scientific, and how much did they cost (see sub-paragraph F(iii) above)?
7. Is the Test designed to be administered by medical and healthcare professionals?
8. What would approval from CLIA in the United States and accreditation from NATA in Australia facilitate in terms of the provision of the Test?
9. Please provide a copy of GTG's correspondence with the following parties (not for release to the market)¹:
- a) Major manufacturers (including Thermo Fisher Scientific) confirming capacity to scale up production of the Test (see sub-paragraph F(iv) above).

¹ The fact that ASX tells a listed 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.

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- b) Several international biobanks and clinical laboratories in relation to the sourcing of an independent cross-validation dataset (see sub-paragraph F(ii) above).
- c) CMS, CLIA and NATA (see sub-paragraph F(vi) above).
10. How many GeneType for Breast Cancer tests and GeneType for Colorectal Cancer tests has GTG sold to date, and how much revenue has been derived from those sales?
11. Has GTG's genetic testing laboratory been utilised as a high-throughput Covid-19 testing laboratory (see sub-paragraph B(i) above)?
- If the answer to this question is 'yes'. How many tests has GTG processed to date, and how much revenue has GTG derived from the provision of this service?
12. ASX notes that GTG appears to have the in-house capacity to produce or conduct between 250,000 and 360,000 tests per annum (see sub-paragraphs B(iii) and F(v) above).
- Please confirm how GTG currently intends to allocate its in-house capacity between producing the GeneType for Breast Cancer test, the GeneType for Colorectal Cancer test and the Test, and conducting Covid-19 testing for the Australian government.
13. Please confirm that GTG is complying with the Listing Rules and, in particular, Listing Rule 3.1.
14. Please confirm that GTG's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of GTG 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 AEST on Wednesday, 22 July 2020**. You should note that if the information requested by this letter is information required to be given to ASX under Listing Rule 3.1 and it does not fall within the exceptions mentioned in Listing Rule 3.1A, GTG's obligation is to disclose the information 'immediately'. This may require the information to be disclosed before the deadline set out in the previous paragraph.

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.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to GTG'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 GTG'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.

Questions

If you have any questions in relation to the above, please contact me.

Yours sincerely

Melissa Kostopoulos

Compliance Adviser, Listings Compliance (Melbourne)