

ASX Market Announcement

GTG signs 3-year US co-exclusive licence agreement for COVID risk test

Melbourne, Australia, 3 March 2021: Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, “Company”, “GTG”), a diversified Genomics and AI driven preventative health business is pleased to announce a co-exclusive production and distribution rights and license agreement (‘Agreement’) with US Based Infinity BiologiX LLC (‘IBX’), a leading central laboratory providing sample collection and processing, storage, analytical services, and scientific and technical support, for the production, distribution and sale of the Company’s COVID-19 Serious Disease Risk (sdr) Test (‘**COVID-19 Risk Test**’) in the United States.

Overview

- Initial three-year co-exclusive licence agreement between IBX and GTG for the production, distribution, sales and marketing of GTG’s COVID-19 Risk Test in the US, under the ‘powered by GeneType’ branding
- IBX is required to make minimum payments to GTG totalling US\$2.9 million over the term to maintain exclusivity with an initial upfront payment of US\$50k followed by minimum payments totalling US\$850k in the first year and US\$1.0 million in each of the second and third years^{1,2}
- IBX may terminate this agreement at any time and for any reason upon 60 days written notice to GTG with effect upon the expiry of the 60-day period
- IBX currently has the capacity to process over 100,000 COVID-19 Risk Tests per day across its two major labs and is well-positioned with an existing network of SARS-CoV-2 testing partners and associated medical practitioners across the US to be able to use GTG’s COVID-19 Risk Test in conjunction with these existing third-party SARS-CoV-2 Tests
- Underlying royalty structure is on a per unit basis of US\$10²
- IBX will define and decide the sales and end-to-consumer pricing structure for the COVID-19 Risk Test

¹ Subject to certain payment provisions allowing IBX to average sales volumes over subsequent quarters

² Refer to Appendix for further details on payment and royalty structure

Genetic Technologies have secured a co-exclusive three-year licence agreement for the production, sale and distribution of its COVID-19 Risk Test across the United States with IBX, subject to IBX's rights to early termination on 60 days' notice. The payment structure includes an initial upfront payment of US\$50k followed by minimum payments totalling US\$850k in the first year and US\$1.0 million in each of the second and third years totalling a minimum US\$2.9 million to maintain exclusivity. Further details on the agreement are outlined in the Appendix to this announcement covering key terms and other provisions.

IBX has three well-established labs, with two labs in New Jersey and one in Minnesota and a network of SARS-CoV-2 testing partners, with access to testing sites across the country providing a clear pathway for the sale and distribution of GTG's COVID-19 Risk Test.

GTG's COVID-19 Risk Test may enable the risk assessment of an individual developing a serious disease should they contract the SARS-CoV-2 virus. The COVID-19 Risk Test is intended to predict 'disease severity' using a combination of genetic and clinical information.

Simon Morriss, CEO of Genetic Technologies, stated: 'We are excited to be partnering with IBX, to enable our COVID-19 Risk Test to be introduced commercially into the COVID-19 product landscape in the US. This agreement is a significant milestone for GTG representing the first multi-year commercial agreement the Company has entered into for the sale and distribution of one of its developed products.

"Our COVID-19 Risk Test is designed to provide individuals with the ability to understand their personal risk associated with contracting a serious case of this disease. Alongside existing treatment options and vaccines, we believe this test will enable more insightful decisions for states, workplaces and individuals on pathways forward in managing this pandemic."

IBX is a market-disrupting central laboratory supporting academia, government, and industry. IBX provides global sample collection, processing, storage, and analytical services integrated with scientific and technical support in both the research and clinical arenas. As a leader in biomaterials, IBX provides support to the development of diagnostics, therapeutics, and research in the genomics, precision, and regenerative medicine arenas.

IBX launched its SARS-CoV-2 saliva-test in May 2020, after receiving FDA Emergency Use Authorization. It was the first test to utilise saliva as the primary biomaterial for SARS-CoV-2, and IBX subsequently became the first company to offer an at-home collection with this approach.

Robin Grimwood, IBX Chief Executive Officer, stated: “We view this initial agreement for the sale and distribution of Genetic Technologies’ COVID-19 Risk Test as a critical collaboration in line with our mission to understand the genetic causes of common, complex diseases and to discover diagnoses, treatments and, eventually, cures for these diseases. We are uniquely and strategically positioned with our partners to deliver the COVID-19 Risk Test and provide remote telehealth services and reporting, utilising our extensive array capability and capacity across a number of platforms. We were proud to offer the first COVID-19 PCR saliva test last spring and now see the COVID-19 Risk Test as an important next step with providing patients with the information they need to make the best decisions possible for their own health, their family’s health and the health of their community.”

The GTG team are in final stages to submit the COVID-19 Risk Test for clearance from Clinical Laboratory Improvement Amendments (CLIA) and will update the market as and when clearance is received.

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Authorised by the Board of Genetic Technologies

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About Genetic Technologies Limited

Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE) is a diversified molecular diagnostics company. GTG offers cancer predictive testing and assessment tools to help physicians proactively manage patient health. The Company's lead products GeneType for Breast Cancer for non-hereditary breast cancer and GeneType for Colorectal Cancer are clinically validated risk assessment tests and are first in class. Genetic Technologies is developing a pipeline of risk assessment products.

For more information, please visit www.gtglabs.com

About Infinity BiologiX LLC:

Infinity BiologiX (IBX) is a market-disrupting central laboratory supporting academia, government, and industry. IBX provides global sample collection, processing, storage, and analytical services integrated with scientific and technical support in both the research and clinical arenas. As a leader in biomaterials, IBX provides support to the development of diagnostics, therapeutics, and research in the genomics, precision, and regenerative medicine arenas. IBX previously operated as RUCDR Infinite Biologics before spinning off from Rutgers University-New Brunswick in August 2020.

For more information, visit www.ibx.bio

Appendix – Key Terms of the ‘Agreement’

GTG grants to IBX a co-exclusive right and license to develop and optimise, market, advertise, sell, and distribute the COVID-19 Risk Test in the US. And to perform and use the COVID-19 Risk Test in IBX and affiliate’s laboratories or other facilities; and to generate and use any reports or other information based on the performance of the COVID-19 Risk Test, including reports and information that include the results of analysis based on the COVID-19 Risk Test.

Initial Term: Three Years commencing on the Effective Date

Effective Date: 1 March 2021

Termination: IBX may terminate this agreement at any time and for any reason upon 60 days written notice to GTG with effect upon the expiry of the 60-day period.

Further standard termination provisions apply for both GTG and IBX which cover material breaches, insolvency and cover protection of intellectual property.

Renewal: Automatic successive one-year terms

Payment Terms:

Upfront Fee - Within 14 days after the Effective Date, IBX will pay to GTG a non-refundable fee of US\$50,000

Minimum Fees - IBX will pay to GTG \$100,000 within 60 days of the end of the first calendar quarter following the first commercial sale of the first COVID-19 Risk Test during the term of this Agreement (First Quarter) and, if such first quarter shall be less than three (3) months, the amount payable shall be reduced proportionally to the time that had elapsed in such calendar quarter preceding the Effective Date; and \$250,000 within 60 days of the end of each calendar quarter following the First Quarter.

Royalty Structure:

IBX shall pay to GTG a royalty equal to US\$10 per commercial COVID-19 Risk Test performed by IBX in the Territory during the Term for such calendar quarter (less the amount of any previously uncredited Minimum Fees paid). IBX shall make such royalty payments to GTG within sixty days after the end of each calendar quarter during the Term, and each payment shall be accompanied by a report setting forth the number of COVID-19 Risk Tests performed by IBX for the applicable calendar quarter and the royalties payable to GTG.

Pricing:

IBX will define and decide the sales and end-to-consumer pricing structure for the COVID-19 Risk Test.

Intellectual Property Protections:

Each party shall continue to own all of the intellectual property rights owned by it prior to the Effective Date or developed or acquired by it after the Effective Date independent of the activities under this Agreement, except that GTG shall own all the Intellectual Property subsisting in the GTG Technology and Improvements.

IBX shall own all other Intellectual Property it generated or developed as a result of its activities under this Agreement, including development of process and laboratory improvements and procedures and protocols related to the COVID-19 Risk Test.

IBX shall be entitled to freely sublicense its co-licensing rights under the Agreement.