

Genetic Technologies Q3 FY'22 Results

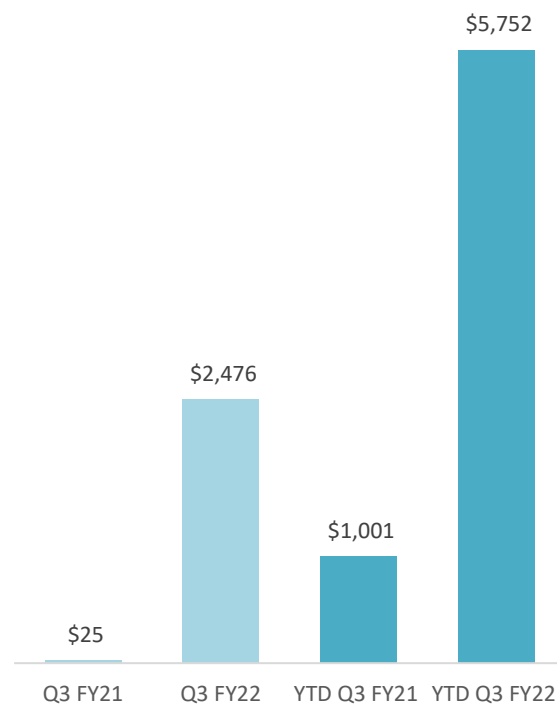
Regulatory approvals, patent granted and revenue growth

Melbourne, Australia, 8 April 2022: Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, “Company”, “GTG”), a global leader in genomics-based tests in health, wellness and serious disease provides its results for the quarter ended 31 March 2022 (“Quarter”).

Highlights

- Year to date growth in revenue of 475%
- Cash receipts of A\$2 million, an increase of 9% on the prior quarter, and mainly comprising EasyDNA product sales
- GeneType Multi-Risk Test received NATA¹ accreditation and CMS² certification
- Phase 1 of geneType Multi-Risk Test launched for physicians targeting 50% of annual mortalities and morbidities in six serious diseases including: breast cancer, colorectal cancer, prostate cancer, ovarian cancer, coronary artery disease and type-2 diabetes
- Launched our Virtual Sales Rep (VSR) with Hahn Healthcare in the Australian with sales support the creation of our GeneType Hubs
- US Patent granted for COVID-19 Risk Test, enabling GTG to expand commercialisation opportunities
- Leveraging EasyDNA acquisition by progressing a ‘One company two brands’ strategy
- Sound cash balance of A\$11.43³ million, providing 21 months⁴ runway for investing in growth initiatives

Revenue (A\$'000)



¹ National Association of Test Authorities, Australia

² US Centers for Medicare and Medicaid Services

³ Excludes A\$1.44m R&D Tax Incentive received on April 2, 2022

⁴ Based on latest Company cashflow projections

Genetic Technologies is in a strong position with a portfolio of high-quality products both in the market and under development and a substantial international platform for the distribution of the Direct-to-Consumer product base via EasyDNA.

Important progress was made during the Quarter on two of the Company's core geneType growth products. The geneType Multi-Risk Test receiving approval for commercial release, while the US Patent Office granted a US patent for the geneType COVID-19 Risk Test. These milestones are an important step towards commercialisation for both products.

Commenting on the quarter, CEO Simon Morriss stated: "During the last quarter the company has successfully executed a number of major milestones. Including approvals, in both Australia and the US, for our geneType Multi-Risk Test. These approvals have enabled GTG to initiate the commercialisation of the Multi-Risk Test to physicians in Australia and the USA."

"Our recent acquisition of EasyDNA provides us an excellent channel to drive sales and product awareness, and I am pleased to report the contribution of cash receipts from EasyDNA increased by 9% to A\$2m during the March '22 quarter versus December '21 quarter. We remain focused modernising the brand, improving the user experience in our EasyDNA platform and on continuing to opening up new channels and markets to drive further revenue growth through our exciting product and brand offerings."

"We are also very pleased to announce the granting of a US patent for our COVID-19 Risk Test. The granting of this patent provides a strong foundation for the ongoing commercialisation of our COVID-19 Risk Test. This test can make a meaningful contribution to the management of the COVID-19 pandemic by helping to provide improved health outcomes for patients at risk of developing severe COVID-19 disease.

Commercial and Product Overview

The Company's strategy to commence commercialisation and enhance the product distribution network is well underway. Key avenues for commercialisation of launched products currently include the consumer-initiated testing and online sales and marketing platform available in Australia and the US. With the recent inclusion of the EasyDNA business the Company intends to leverage this platform to enhance the awareness and availability of its existing products.

GeneType Multi-Risk Test Approved for Commercial Release, Phase One Roll-Out Launched

During February, GTG's geneType Multi-Risk Test received simultaneous NATA accreditation and CLIA -certification from the US Centers for Medicare and Medicaid Services (CMS). These critical approvals have enabled the launch of Multi-Risk Test. The initial launch phase will focus on risk assessments for six serious diseases that together represent around half of all annual morbidities in the US⁵: Breast Cancer, Colorectal Cancer, Prostate Cancer, Ovarian Cancer, Coronary Artery Disease and Type-2 Diabetes. The tests will be available to purchase individually or as a bundle. Additional disease candidates will follow in planned future phases.

The Multi-Risk Test represents an important step towards the development of personalised, preventative healthcare, enabling patients and their healthcare professionals to develop a long-term health plan. GTG's commitment to providing integrated risk tests such as the Multi-Risk Test builds on the foundation of the rapidly expanding area of Precision

⁵ <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

Medicine⁶, which was worth US\$26 billion in 2021 in North America⁷. This segment of medicine provides a precise pathway to medical care with a potentially significant improvement in health outcomes for patients.

GeneType Commercialisation Strategies

Reimbursement - USA

GTG have engaged ALVA10, a Boston USA based consulting company that have developed a unique expertise in determining the level of evidence required for US payers to provide coverage for diagnostic tests. US payors include Medicare, and large US employer groups. ALVA10 are in the final stages of developing a Budget Impact Model (BIM) that can translate our geneType breast cancer risk assessment test into a format that can be assessed within the US healthcare system. This is our first step toward obtaining US payers coverage: obtaining such coverage would be a 'game-changing' achievement for GTG facilitating and accelerating broad adoption of geneType.

Initial feedback from the BIM shows implementation of the geneType breast cancer risk assessment test increases supplemental screening and an increase in early-stage detection from 54% to 61% of cases. Potential savings of US\$83k per patient could be achieved by moving from a cancer stage (2b or later) to earlier stage diagnosis. BIM calculates an overall reduction in cancer with increased use of risk-reducing medication in indicated patients, which could contribute to substantial cost savings for US payers.

The BIM will be completed in the coming quarter, including the drafting of a manuscript in support of reimbursement and commercialization model for payers and insurers to review.

Australian Sales Strategy

Hahn Healthcare have been engaged and launched our Virtual Sales Rep (VSR) in the Australian General Practice with sales management support targeting 2,000 general practice clinics with > 6 GPs which represent > 80% of all consultations. Our goal of developing clinical practices into 40-50 "geneType Hubs". With the support of our clinical and medical team we have developed an "Early Access Program" enabling clinical practices to offer their first 10 patients testing at no-charge. GTG is optimistic that the combination of geneType's strong predictive clinical utility and Hahn Healthcare's deep reach into Australian medical centres will accelerate adoption and drive growth of the test in the Australian market.

US Patent Office Grants Patent for COVID-19 Risk Test

During the Quarter GTG was granted a US patent for the geneType COVID-19 Risk Test. The patent covers the proprietary technology incorporated in the test, which provides a probability that a person will develop severe symptoms requiring hospitalisation should they become infected with COVID-19.

The granting of the patent is an important step for the Company to secure commercial opportunities for the geneType COVID-19 Risk Test. In conjunction with its partners, GTG will continue to progress sales and marketing endeavours and potentially provide improved health outcomes for patients at risk of developing severe COVID-19 disease.

The geneType COVID-19 Risk Test is designed to predict disease severity using genetic and clinical information providing a risk score that can be used to understand a person's risk of contracting a serious case of COVID-19. In addition, employers, governments, and other public health entities may use the data to make informed decisions about disease risk, treatment options, and importantly guiding vaccination and booster priorities.

⁶ A form of medicine that uses information about a person's own genes or proteins to prevent, diagnose or treat disease

⁷ https://www.graphicalresearch.com/industry-insights/1954/north-america-precision-medicine-market?gclid=CjwKCAiAgbiQBhAHEiwAuQ6Bknb6EDXUsrZaLB3xAlfsIXwfiA8NXT1RvL-isswTg0mlwSITIHcwnxoClnEQAvD_BwE

According to the Centers for Disease Control and Prevention, only 71.2% of the US population is fully vaccinated, leaving approximately 95 million Americans partially or completely unvaccinated. The geneType COVID-19 Risk Test could assist these people to better understand their risk of severe disease, while providing those who are vaccinated (approximately 235 million people) with an understanding of the necessity to obtain a booster if they are at high risk of severe disease.

Research and Publications

During the quarter the Company's cross-validation study confirming the geneType COVID-19 Risk Test performance metrics on a European data set was accepted for publication in "Epidemiology and Infection" with an expected publication date of in April 2022. In the coming quarter, our Scientific team are preparing manuscripts for publication to support clinical validity for each of the tests in the phase 1 launch of the Multi-Risk Test.

Research and Development Tax incentive

On April 2, 2022, the Company received a A\$1.44 million research and development (R&D) tax incentive payment from the ATO. The payment was in respect of eligible research and development expenditure incurred during the financial year ended June 30, 2021.

Corporate and Financial Overview

Cash receipts from customers for the March quarter totalled A\$1.97 million, an increase of 8.7% on the prior quarter. Receipts comprised A\$1.94 million from EasyDNA product sales (+7% on the prior quarter), and A\$27k from GeneType sales for Breast Cancer and Colorectal Cancer products (up from A\$3k in the prior quarter).

Cash outflows used in operating activities were A\$2.1 million. In addition to cash receipts from customers detailed above, grants and interest received were A\$9k. Expenses incurred on a cash basis during the quarter included research and development and staff costs of A\$1.2 million associated with the geneType product development. Additionally, the Company incurred A\$576k associated with advertising and marketing with expenditure expected to increase as the company enhances its sales and marketing focus on the geneType brand in future quarters.

The Company remains well capitalised, with March '22 quarter end cash and cash equivalents of A\$11.4 million, providing adequate runway to support the commercialisation initiatives for the geneType brand. The Company received an R&D tax incentive payment of A\$1.44 million from the ATO on April 2, 2022 in respect of its 2021 financial year. Including this receipt, the Company has cash reserves of A\$12.8 million at quarter end.

During the March 2022 quarter, net cash payments to directors were A\$68k comprising A\$51k as director fees and A\$17k as consulting fees.

Outlook

The Company remains focused on the commercialisation opportunities for the Multi-Risk Test, continued leveraging the EasyDNA brand and product suite to grow the revenue base, further investment in R&D to enhance our Multi-Risk Test offering and COVID-19 Risk Test and continuing to remain at the cutting edge of genetic testing and preventative health. Commenting on the forward outlook, Simon Morriss stated: "We are very pleased with the progress made over this quarter in achieving approvals for Multi-Risk Test and the patent for the COVID-19 Risk Test. Quarter four focus will be on the significant opportunity of our geneType product suite; continuing to demonstrate the clinical validity and utility of the geneType tests in the healthcare sector; and EasyDNA sales growth by expanding our product offering through new markets and channels.

Authorised for release by the Board of Genetic Technologies Limited

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Investor Relations

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About Genetic Technologies Limited

Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE) is a diversified molecular diagnostics company. A global leader in genomics-based tests in health, wellness and serious disease through its geneType and EasyDNA brands. GTG offers cancer predictive testing and assessment tools to help physicians to improve health outcomes for people around the world. The company's Polygenic Risk Scores (PRS) platform is a proprietary risk stratification platform developed over the past decade integrating clinical and genetic risk delivering actionable outcomes from physicians and individuals. Leading the world in risk prediction in Oncology, Cardiovascular and Metabolic diseases. Genetic Technologies continues to develop a pipeline of risk assessment products.

For more information, please visit www.genetype.com

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Genetic Technologies Limited

ABN

17 009 212 328

Quarter ended ("current quarter")

31 March 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,967	4,626
1.2 Payments for		
(a) research and development	(23)	(226)
(b) product manufacturing and operating costs	(1,405)	(2,785)
(c) advertising and marketing	(576)	(1,597)
(d) leased assets	(106)	(328)
(e) staff costs	(1,221)	(3,652)
(f) administration and corporate costs	(701)	(2,280)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	9	24
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	66
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(2,056)	(6,152)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	(3,472)
(c) property, plant and equipment	-	(17)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	(3,489)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	-	-

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	13,509	20,903
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,056)	(6,152)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(3,489)

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(103)	88
4.6	Cash and cash equivalents at end of period	11,350	11,350

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	4,307	4,965
5.2	Call deposits	7,043	8,544
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	11,350	13,509

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	68
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

During the quarter, the Company made payments to related parties of the entity and their associates as disclosed in Item 6.1 of the Appendix 4C amounting to \$68k. The payments related to the net pay of salaries, directors fees and consulting fees (inclusive of GST) on normal commercial terms.

Quarterly cash flow report for entities subject to Listing Rule 4.7B

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	190	0
7.4 Total financing facilities	190	0
7.5 Unused financing facilities available at quarter end		190
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
1. Secured – Bank of America, US\$25,000 facility with interest at 9.25% 2. Unsecured – National Australia Bank, \$150,000 facility with interest at 15.5%		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,056)
8.2 Cash and cash equivalents at quarter end (item 4.6)	11,350
8.3 Unused finance facilities available at quarter end (item 7.5)	190
8.4 Total available funding (item 8.2 + item 8.3)	11,540
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.6
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 8 April 2022

Authorised by: Mike Tonroe
Company Secretary

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.