Genetic Technologies

GTG.ASX, GENE.US



A research platform of MST Financial

2 May 2023

Solid 3Q results; rapidly growing clinical utility for geneType test

NEED TO KNOW

- Cash receipts up substantially
- GeneType testing volume growing strongly
- Increasing clinical utility as Multi-Test Panel expands

Cash receipts strong, testing momentum healthy: Genetic Technologies (GTG) has released its results for 3QFY23, with solid numbers (including strong revenue growth) indicating that the company remains on track. Year-to-date customer cash receipts of \$6.7m were up 45% vs. the prior corresponding period (pcp), with 3Q cash receipts up 13% year on year (yoy). GTG highlighted that testing volume for geneType doubled from February to March, with similar growth in April. GTG attributed this growth to the appointment of Medical Science Liaison (MSL) personnel across Australia to drive sales nationwide.

GeneType's increasing clinical utility is the key development: GTG outlined its achievements from 3Q, most notably the expansion of its Multi-Test Panel to include 9 diseases – a substantial achievement opening significant opportunities for GTG. Also notable in 3Q: its strategic alliance with QIAGEN, multiple published peer-reviewed studies validating geneType, continued US payer engagement in pursuit of reimbursement and the upcoming launch of a world-first comprehensive breast/ovarian cancer risk assessment test.

Investment Thesis

GeneType platform – a comprehensive risk score: GTG's geneType platform integrates genetic information with traditional clinical risk factors to predict a person's chance of developing disease in the future via patented algorithms. Tests use patient genetic variants known as SNPs to calculate a Polygenic Risk Score (PRS), which when combined with traditional clinical and familial risk factors produce a Comprehensive Risk Score (CRS). The CRS indicates a patient's predisposition to developing the disease in the future (5-year risk and lifetime risk), and can be used to inform clinical decisions, improve current screening techniques and indicate further screening (although it cannot detect disease and thus is not a screening tool per se).

Building on first-mover advantage in breast cancer: GeneType for breast cancer improves on GTG's earlier breast cancer risk assessment products, incorporating multiple additional clinical risk factors and predicting the patient's 5-year and lifetime breast cancer risk. We think GTG's first-mover advantage in breast cancer risk assessment, clinical supporting data and substantial market opportunity make geneType for breast cancer fundamental to GTG's investment case and a proof of concept for the geneType platform overall. Health economic benefits of geneType for breast cancer should support reimbursement coverage in the US which, if achieved, could be a major catalyst for adoption.

GTG's CLIA-certified lab supports path to market: CLIA certification supports fast new product development and lets GTG market products directly into the US.

Valuation

We value GTG at A\$118m or A\$0.01/share (diluted), using DCF methodology on free cash flow and using 11,546m shares and 274m options/warrants on issue.

Equities Research Australia

Pharmaceuticals, Biotechnology and Life Sciences

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Genetic Technologies (GTG) is an ASX-listed molecular diagnostic company focused on disease risk prediction. The company uses polygenic markers of risk combined with clinical factors to predict risk of disease. The introduction of geneType Multi-Risk Test (incorporating geneType for breast cancer for non-hereditary breast cancer and geneType for colorectal cancer), along with the recent acquisition of DNA-based products, underpins a broad, complementary portfolio of genomic-based tests, creating a significant competitive advantage. GTG operates in the USA, Europe, and Asia Pacific under various revenue models.

https://www.genetype.com

Valuation A¢ 1.0 (previously A¢1.2)

Current price A¢ 0.3

Market cap A\$35m

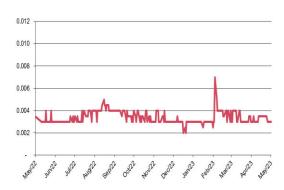
Cash on hand A\$10.5m (31 March 2023)

Upcoming Catalysts/Newsflow

Period

Short term Securing a commercial pilot study agreement

Share Price (A\$)

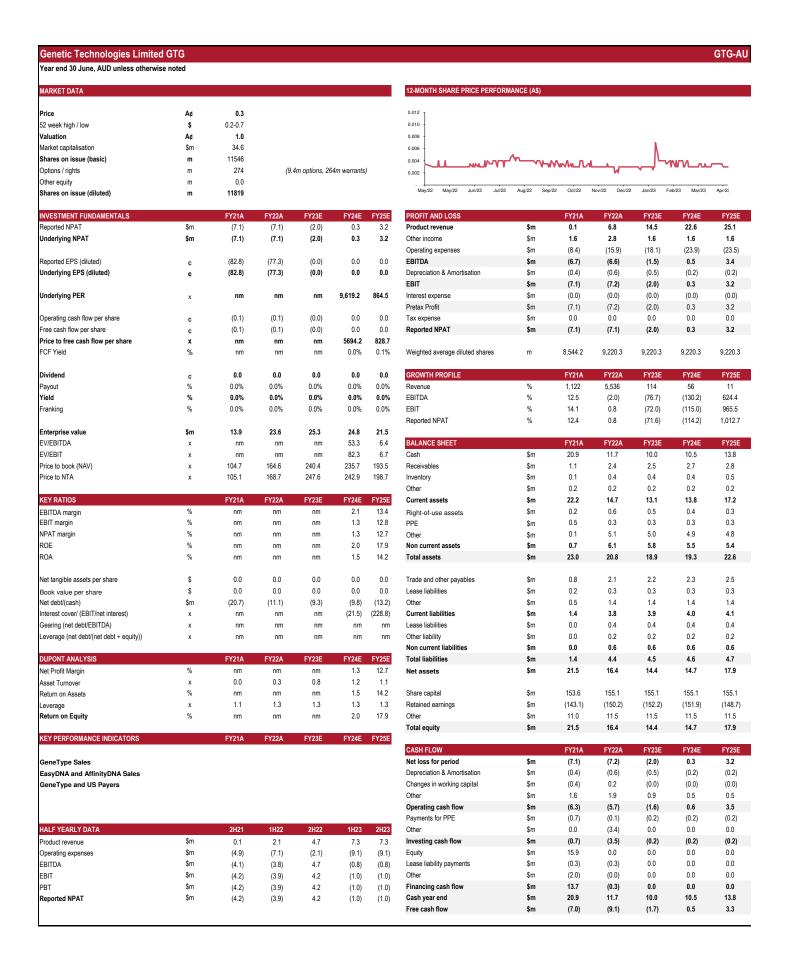


Source: FactSet, MST Access.

Risk

Risks include IP, shareholder dilution, competition, and management retention.

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Round-up of 3Q Highlights: Clinical and Business Wins Demonstrate that GTG is On Track

GTG highlighted its major achievements during the quarter in its 3Q release. The company has made progress on the clinical front as well as with respect to commercial and business development.

Clinical highlights

Expanding indications on geneType Multi-Test Panel: We believe the key achievement of GTG over recent months is the rapid expansion of the number of indications on its geneType platform. The tests available on the Multi-Test Panel have increased to 9 (with 3 new diseases added in the newest phase: melanoma, pancreatic cancer and atrial fibrillation). This increase speaks to a substantial improvement in the clinical utility of the test. We expect that the growth in the scope of the Multi-Test Panel will drive momentum in take-up of the test.

Comprehensive Risk Assessment Test to evaluate risk of both breast and ovarian cancer: GTG is also launching a comprehensive, clinically validated risk assessment test for breast and/or ovarian cancer. This one saliva test assesses a woman's risk of developing these cancers by checking gene mutation, hereditary and sporadic indicators and other relevant clinical risk factors. The assessment covers disease caused by monogenic factors (traditional germline testing such as BRCA) which accounts for ~5% of these cancers, familial factors (~10%) and sporadic factors (~85%) to assess the overall risk. The test will incorporate next-generation sequencing techniques to assess risk. It will be launched through GTG's business-to-business and consumer-initiated testing channels and will be showcased at the BRCA 2023 Symposium in early May.

Peer-reviewed studies validate geneType's clinical utility: 3 publications (across 3 peer-reviewed journals) were accepted during the quarter, bringing the total to 5 in the past six months. The studies cover a number of indications: ovarian, breast and prostate cancer; cardiovascular disease; and type 2 diabetes.

Commercial and business development highlights

Revenue growth underpinned by meaningful presence in large US market: The company has indicated that its volume and revenue growth has been strong year to date, and that 60% of its test volumes come from the US, with the remainder from Australia. Traction in the very large US market presents meaningful opportunities for strong growth.

Continuing discussions with US payers to seek reimbursement: GTG is actively engaged with 11 US payer groups with a combined coverage of 42m Americans, with a view to obtaining reimbursement from these key players. Additionally, the company is targeting employer groups, with whom the company plans a commercial pilot study to start in 2H2023. The aim of the study is to show the benefit of geneType for the members of the employer groups.

Partnership with QIAGEN to open new commercial opportunities: GTG has formed a strategic alliance with molecular testing company QIAGEN with a plan to establish a 'centre of excellence' facility in Australasia. GTG expects the partnership will generate new commercial opportunities, increased automation capability and greater capacity, as well as unlock the Australian reimbursable market across testing categories, all of which it anticipates will support revenue growth.

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