



GENETIC TECHNOLOGIES LIMITED

A.B.N. 17 009 212 328

Quarterly Activities Report
and
Appendix 4C of the ASX Listing Rules
for the quarter ended
31 December 2010

GENETIC TECHNOLOGIES LIMITED

QUARTERLY ACTIVITIES REPORT FOR THE QUARTER ENDED 31 DECEMBER 2010

OPERATIONS

Cash receipts from customers during the quarter ended 31 December 2010 were up significantly on the previous quarter to \$10.8 million due largely to receipts from a number of new non-coding licenses that were granted to parties, together with solid performance from the Company's genetic testing operations (refer below). Pleasingly, total cash receipts for the half-year ended 31 December 2010 exceeded \$14.2 million which compares most favourably with the total cash receipts for the previous full financial year ended 30 June 2010 of \$10.1 million.

At 31 December 2010, the Company's cash reserves were approximately \$8.4 million, an impressive 155% increase over the corresponding balance at 30 June 2010 of \$3.3 million.

Revenues from the Company's testing operations for the half-year under review were almost exactly on budget, after minor adjustments for delays in the launch of the Company's BREVAGen™ product in the US (refer below). A program of ongoing cost reduction initiatives decreased costs to well below budget expectations.

For the first time in the Company's history, it is expected that Genetic Technologies will generate a maiden net profit for the first half of the 2011 financial year, once final adjustments are processed as part of the Company's half-year audit in February. The Company's final financial results will be disclosed in the Company's ASX Appendix 4D in late February.

Pre-launch preparation for BREVAGen™ breast cancer test

During the quarter, the Company's Melbourne-based laboratory prepared the necessary documentation to gain approval to sell tests in the US through a validation package provided to the CMS (Centers for Medicare and Medicaid Services) in New York City. Preliminary responses from the US have indicated that the validation package has satisfied the requirements for granting GTG's laboratory certification under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It is anticipated that a formal response will be received in the first quarter of the 2011 calendar year and, if approved, Genetic Technologies will be the first and only laboratory in Australia to be certified under CLIA and one of only a handful outside the US.

The development and expansion of the Phenogen Sciences operations in the US continued during the quarter ahead of the anticipated BREVAGen™ launch in March 2011. A key focus of this work related to the recruitment of the first members of the US sales team as well as further discussions with Key Opinion Leaders and the creation of a marketing campaign for the BREVAGen™ product. Test and kit materials have been produced and the complex processes necessary for reimbursement in the US have been developed with the Company's US-based consultant, Premier Source. Preparation of other important documents required for the launch, including those relating to transfer pricing issues, is also well underway.

In October 2010, the prestigious *Journal of the National Cancer Institute* published a peer reviewed article favourably supporting the BREVAGen™ test, particularly for women at intermediate risk.

Australian market

In the medical diagnostics area, discussions took place during the quarter with the NSW Police Force regarding an option to extend the existing forensic services contract for another year to undertake "complex volume crime" testing. The decision has been taken to transfer the "simple complex crime" work back to the NSW Department of Analytical Laboratories now that GTG has eliminated the previous backlog of testing. GTG has been praised for the high quality of its work and its superior turnaround times to make this project successful. Furthermore, GTG has now been asked to investigate other areas where it may be able to meet the forensic needs of NSW Police.



Quarterly Activities Report for the quarter ended 31 December 2010

OPERATIONS (cont.)

Also during the December quarter, GTG was successful in securing a contract with the Malaysian Breast Cancer Centre (CARIF) for the exclusive provision of BRCA testing.

In the animal area, a contract has been secured by the Company in the Philippines through the largest provider of micro chipping, Plaridel, for GTG to provide various genetic testing services. The China Kennel Union contract period also began with staff training and attendance at key dog shows in the Beijing area.

LICENSING AND IP

The Company's intellectual property portfolio, which includes the patents acquired from Perlegen Sciences Inc., continues to strengthen, with 108 patents now granted and a further 84 pending.

Assertion programs

On 16 February 2010, the Company announced it had filed a patent infringement suit in respect of its non-coding DNA technologies against nine parties in the US District Court, Western District of Wisconsin. The counter-parties are Beckman Coulter Inc., Monsanto Company, Interleukin Genetics Inc., Orchid Cellmark Inc., Gen-Probe Inc., Molecular Pathology Laboratory Network Inc., PIC USA Inc., Sunrise Medical Laboratories and Pioneer Hi-Bred International Inc.

Since then non-coding licenses have been granted to each of the following seven parties as part of settlements with those parties:

- Gen-Probe Inc.
- Molecular Pathology Laboratory Network Inc.
- Monsanto Company
- Beckman Coulter Inc. (incorporating Clinical Data Inc.)
- Interleukin Genetics Inc.
- Pioneer Hi-Bred International Inc.
- Sunrise Medical Laboratories

Total gross fees generated from the granting of the above licenses are over **\$4.7 million**. Further, settlement discussions with the remaining two parties have commenced.

On 20 January 2011, the Company announced it had filed a further patent infringement law suit in the US, this time in the US District Court, Western District of Texas, Austin Division. The counterparties to this new action, each a company associated with Sonic Healthcare Limited ("Sonic"), are:

- Clinical Pathology Laboratories Mid-Atlantic of Chantilly, Virginia
- Clinical Pathology Laboratories Southeast of Orlando, Florida
- Clinical Pathology Laboratories of South West Austin, Texas
- PathLabs of Toledo, Ohio
- East Side Clinical Laboratories of East Providence, Rhode Island
- AEL of Memphis, Morristown; Lebanon, Tennessee and Columbus, Mississippi

This second infringement suit follows the recent settlement between GTG and Sunrise Medical Laboratories which is also associated with Sonic.

Both of the above cases are being prosecuted by the Company's Colorado-based law firm Sheridan Ross PC which has previously asserted and defended GTG's intellectual property rights and has assembled a team to support the case. GTG has put in place arrangements pursuant to which the Company believes that the patent infringement suits should not have a material adverse impact on its finances.

LICENSING AND IP (cont.)

Other licensing activities

In addition to the licenses granted in settlement of the first patent infringement suit above, the Company is actively pursuing licenses in jurisdictions other than the US, principally in Europe. During the December quarter, the Company successfully concluded licensing deals with the following three European parties which collectively generated gross fees of nearly **\$6.4 million**:

- The Company executed a Settlement and License Agreement with the global biotechnology company, QIAGEN NV of Hilden, Germany under which QIAGEN has been granted non-exclusive rights to a number of GTG patents, including non-coding analysis, gene mapping and internal standards.
- GTG settled a dispute relating to its non-coding patents following the legal action initiated by it against Innogenetics NV of Ghent, Belgium. As part of this resolution, Innogenetics entered into a Settlement Agreement with GTG, and the matters that were formerly in dispute were resolved.
- GTG granted a license to its non-coding patents to Laboratoires Réunis of Luxembourg.

Overall, the December quarter under review continued to deliver positive results for the Company's licensing program, with total gross revenues generated from licensing during the first half of the 2011 financial year exceeding **\$11.6 million**. It is anticipated that further licenses will continue to be granted in coming months.

RESEARCH AND DEVELOPMENT

As part of the Company's stronger focus on the cancer diagnostic area, its three research programs are progressing via co-commercialisation or partnering.

- The **RareCollect** project has been presented to a variety of industry players. Discussions with several large international companies interested in pursuing potential commercial collaborations are continuing, with two parties currently undertaking independent third party verification of the RareCollect data.
- An **ImmunAid** proof of concept trial is progressing through the planning phase with a US oncology-focused institution while preliminary commercial discussions with institutional and commercial partners continue. Key GTG personnel visited research institutes in the US and Europe to discuss the next trials to develop the technology further. A key patent in the ImmunAid patent estate was granted during the quarter.
- Following *in vitro* studies of the Company's **Nematode** project, GTG is assessing opportunities for partnering this program with a partner with a strong veterinary focus. This party is currently raising funds for an agricultural investment vehicle that may be interested in taking this project forward with GTG and the MLA.

CORPORATE MATTERS

On 15 October 2010, the Company released its 2010 Annual Report to the Market. Also on that date, the Company released its Notice for the 2010 Annual General Meeting of shareholders which was held on Wednesday, 24 November 2010 in the "Treetops" Room at Melbourne Museum. Copies of both documents can be found on the Company's website at www.gtglabs.com. All resolutions put before the shareholders at the Meeting were passed on a show of hands.

On 15 October 2010, the Company released its 2010 Annual Report.



Quarterly Activities Report
for the quarter ended **31 December 2010**

CORPORATE MATTERS (cont.)

On 22 December 2010, the Company released its 2010 US Annual Report on Form 20-F.

Signed on behalf of Genetic Technologies Limited

Dated this 28th day of January, 2011

DR. PAUL D.R. MacLEMAN
Chief Executive Officer

Appendix 4C

Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001, 24/10/2005.

Name of entity

GENETIC TECHNOLOGIES LIMITED

ABN

17 009 212 328

Quarter ended ("current quarter")

31 DECEMBER 2010

Consolidated statement of cash flows

| | Current quarter (December 2010) \$A | Year to date (six months) \$A |
|---|---|-------------------------------------|
| Cash flows related to operating activities | | |
| 1.1 Receipts from customers | 10,807,177 | 14,219,032 |
| 1.2 Payments for (a) staff costs | (1,312,542) | (2,854,708) |
| (b) advertising and marketing | (70,997) | (154,848) |
| (c) research and development | - | (49,500) |
| (d) leased assets | - | - |
| (e) other working capital | (3,600,173) | (5,785,562) |
| 1.3 Dividends received | - | - |
| 1.4 Interest and items of a similar nature received | 19,663 | 49,902 |
| 1.5 Interest and other costs of finance paid | (35,141) | (48,715) |
| 1.6 Income taxes paid | - | - |
| 1.7 Grant and other income | - | - |
| Net operating cash flows | 5,807,987 | 5,375,601 |

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

Consolidated statement of cash flows (cont.)

| | Current quarter (December 2010) \$A | Year to date (six months) \$A |
|--|---|-------------------------------------|
| 1.8 Net operating cash flows (carried forward) | 5,807,987 | 5,375,601 |
| Cash flows related to investing activities | | |
| 1.9 Payment for the acquisition of: | | |
| a) businesses (item 5) | - | - |
| b) equity investments | - | - |
| c) intellectual property | - | - |
| d) physical non-current assets | (27,506) | (48,988) |
| e) other non-current assets | - | - |
| 1.10 Proceeds from the disposal of: | | |
| a) businesses (item 5) | - | - |
| b) equity investments | - | - |
| c) intellectual property | - | - |
| d) physical non-current assets | 26,958 | 81,050 |
| e) joint venture interest | - | - |
| 1.11 Loans to other entities | - | - |
| 1.12 Loans repaid by other entities | - | - |
| 1.13 Other (provide details if material) | - | - |
| Net investing cash flows | (548) | 32,062 |
| 1.14 Total operating and investing cash flows | 5,807,439 | 5,407,663 |
| Cash flows related to financing activities | | |
| 1.15 Net proceeds from the issue of shares | - | - |
| 1.16 Proceeds from sale of forfeited shares | - | - |
| 1.17 Proceeds from borrowings | - | - |
| 1.18 Repayment of borrowings from third parties | - | - |
| 1.19 Dividends paid | - | - |
| 1.20 Repayment of finance lease principal | (60,662) | (119,992) |
| Net financing cash flows | (60,662) | (119,992) |
| Net increase / (decrease) in cash held | 5,746,777 | 5,287,671 |
| 1.21 Cash at beginning of quarter / year to date | 2,786,467 | 3,306,311 |
| 1.22 Exchange rate adjustments | (105,837) | (166,575) |
| 1.23 Cash at end of quarter | 8,427,407 | 8,427,407 |

+ See chapter 19 for defined terms.

Payments to directors of the entity and associates of the directors
Payments to related entities of the entity and associates of the related entities

| | | Current quarter \$A |
|------|--|------------------------|
| 1.24 | Aggregate amount of payments to the parties included in item 1.2 | 769,009 |
| 1.25 | Aggregate amount of loans to the parties included in item 1.11 | - |

1.26 Explanation necessary for an understanding of the transactions

The amount included at Item 1.24 includes \$61,600 paid to Directors during the quarter in respect of fees and superannuation. The amount also includes outgoings of \$13,730 for the Melbourne laboratory premises paid to an entity associated with a former Director and major shareholder, in addition to \$693,679 in commissions and consulting fees paid in respect of services rendered to the Company by that individual.

Non-cash financing and investing activities

2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

None during the quarter under review

2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

None during the quarter under review

Financing facilities available

Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).

| | | Amount available \$A | Amount used \$A |
|-----|---|-------------------------|--------------------|
| 3.1 | Loan facilities | - | - |
| 3.2 | Credit standby arrangements Hire purchase facility | 2,500,000 | 262,648 |

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

Reconciliation of cash

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows:

- 4.1 Cash on hand and at bank
- 4.2 Term deposits
- 4.3 Bank overdraft
- 4.4 Commercial Bills of Exchange
- Total cash at end of quarter (item 1.23)**

| Current quarter (December 2010) \$A | Previous quarter (September 2010) \$A |
|---|---|
| 7,427,407 | 1,786,467 |
| 1,000,000 | 1,000,000 |
| - | - |
| - | - |
| 8,427,407 | 2,786,467 |

Acquisitions and disposals of business entities

- 5.1 Name of entity
- 5.2 Place of incorporation or registration
- 5.3 Consideration for acquisition or disposal (note)
- 5.4 Total net assets
- 5.5 Nature of business

| Acquisitions (Item 1.9(a)) | Disposals (Item 1.10(a)) |
|-------------------------------|-----------------------------|
| Not applicable | Not applicable |
| | |
| | |
| | |
| | |

Compliance statement

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Sign here: Date: **28 January 2011**
Chief Executive Officer

Print name: **Dr. Paul D.R. MacLeman**

+ See chapter 19 for defined terms.

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
 - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
 - 9.2 - itemised disclosure relating to acquisitions
 - 9.4 - itemised disclosure relating to disposals
 - 12.1(a) - policy for classification of cash items
 - 12.3 - disclosure of restrictions on use of cash
 - 13.1 - comparative information
3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

+ See chapter 19 for defined terms.