

# **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 2009** 

# **GENETIC TECHNOLOGIES LIMITED**

### QUARTERLY ACTIVITIES REPORT FOR THE QUARTER ENDED 31 DECEMBER 2009

#### **OPERATIONS**

Cash receipts from testing customers during the quarter ended 31 December 2009 were \$2.71 million. Revenues from the Company's profiling testing area continues to perform ahead of budget expectations, whilst revenues from the animal testing and reproductive services businesses remained below budget due primarily to delays incurred in the establishment of new facilities in New South Wales, Victoria and Queensland, all of which commenced operations during the December quarter. It is anticipated that these facilities will now generate additional revenues that will assist the Company to meet its budgeted forecasts for the second half of the 2010 financial year.

Encouragingly, whilst revenues from operations have fallen below budget, cost containment initiatives implemented during the year have resulted in a positive variance of almost \$1.5 million in operational costs incurred by the Company for the year to date, as compared to budget.

On 23 October 2009, GTG announced that it had executed an Exclusive Test and Services Agreement with **Rosetta Genomics Inc.** (NASDAQ: ROSG) ("Rosetta"), under which the Company will become the exclusive distributor in Australia, New Zealand and Singapore for Rosetta's microRNA-based assays. Rosetta, whose headquarters are located in Rehovot, Israel, also operates an accredited laboratory in Philadelphia, USA. Under the Agreement, GTG will distribute Rosetta's three recently launched miRview<sup>TM</sup> tests in Australia, New Zealand and Singapore. By leveraging unique biomarkers called microRNAs, Rosetta's miRview<sup>TM</sup> tests can offer patients and physicians new insights on cancer.

On 6 January 2010, GTG announced that it had executed an executed an Exclusive Test Distribution and Services Agreement with **Response Genetics**, **Inc.** (NASDAQ: RGDX), under which Genetic Technologies will become the exclusive distributor in Australia, Indonesia, Malaysia, the Philippines, Singapore and Thailand (collectively, the "Territory") for Response Genetics' ResponseDX: Colon™, ResponseDX: Lung™ and ResponseDX: Gastric™ genetic test panels, proprietary PCR-based molecular diagnostic tests for cancer. Securing the rights to distribute these tests, which offer physicians and their patients an objective way to chart a course of therapy during the period between diagnosis and the start of treatment, is an important further step in GTG's move into advanced cancer management and has expanded the Company's portfolio of genetic tools that enable oncologists to more effectively manage patient diagnosis and therapy, improving treatment outcomes.

Though no new licenses were granted by the Company during the quarter under review, the cash generated by that division from the beginning of the financial year up to the date of this report has now exceeded \$1.5 million. Various negotiations with new parties who may benefit from taking a license to the Company's non-coding technology continue in earnest. The Company continues to actively evaluate how it may extract maximal value from its intellectual property licensing estate and is in active dialogue with parties that may assist with this process.

#### LICENSING AND IP

The Company's intellectual property portfolio continues to strengthen, with 99 patents having now been granted and a further 65 which are pending.

On 30 June 2009, the Company announced that it had been notified by the United States Patent and Trademark Office that a first non-final Office Action relating to one of the Company's patents covering one of its non-coding DNA analysis technologies had been issued. Seven of the thirty six claims of United States Patent number 5,612,179 ('179) are the subject of the re-examination. This initial action is preliminary and non-final. GTG has since filed a response to the action and is awaiting further correspondence. As the re-examination has been initiated *ex parte*, there is no third party to the proceedings. The '179 patent has previously been the subject of several US infringement actions, all resulting in settlement, including one with Applera Corporation.



# Quarterly Activities Report for the guarter ended 31 December 2009

#### RESEARCH AND DEVELOPMENT

The Company's three research programs have all met their respective milestones this year, progressing further towards commercialisation.

- A pilot study by the Company's **RareCellect** project demonstrated the ability to recover whole foetal cells and DNA from cervical mucus, preparing the way for an upcoming Phase Ia clinical study using a novel prototype device and proprietary genetic material enrichment process. If successful, the RareCellect process could eliminate the need for invasive and potentially risky procedures for pregnant women such as amniocentesis. Discussions with large health sector players interested in the program are continuing into a due diligence phase.
- ➤ A further **ImmunAid** trial is now in the planning phase in conjunction with a US oncology-focused institution. A scoping process for a definitive proof of concept trial has been completed, enabling discussions regarding the conduct of such as trial by GTG in conjunction with a partner institution, as mentioned. Early stage commercial discussions with a number of potential commercial and institutional partners continue.
- ➤ In respect of the Company's **Nematode** project, a number of compounds developed under a joint venture program with Meat & Livestock Australia have proved successful *in vitro* in killing parasites of ruminants such as sheep and cattle. In conjunction with commercial parties, the Company is evaluating the ability of the compounds to perform successfully in an environment closer to a real world setting.

#### **CORPORATE MATTERS**

On 5 October 2009, the Company announced the appointment of Dr. Malcolm Brandon as a fourth Director of the Company and a member of the Company's Audit Committee. He has spent his career in the biotech and life sciences sector where he has over 35 years experience in commercially focused research and development and in building successful companies which have commercialised a wide range of Australian and international technologies. As the founding director of the Centre for Animal Biotechnology, Dr. Brandon was also responsible for fund raising and the development of many important agricultural technologies and products. He was co-founder and Director of Stem Cell Sciences Ltd. and Smart Drug Systems Inc. and is currently the Managing Director of genetics and artificial animal breeding company Clone International which uses cloning technologies to breed elite cattle, sheep and horses and to preserve the genetics of elite animals.

On 24 November 2009, Mr. Fred Bart resigned as a Director of the Company and Chairman of its Board of Directors.

On 25 November 2009, the Company held its 2009 Annual General Meeting. Resolution 2, in respect of the re-election of Mr. Bart, was withdrawn following his resignation. All other resolutions that were put to the shareholders were passed on a show of hands.

Also on 25 November 2009, the Company announced the appointment of Mr. Tom Bonvino as a non-executive Director of the Company and a member of the Company's Corporate Governance Committee. He has over 27 years experience in consumer marketing and product development on an International platform and has managed companies for various Italian, Spanish and French firms, distributing and marketing goods throughout South-East Asia. Mr. Bonvino is also currently a non-executive Director of the Melbourne Recital Centre and a Fellow of the Australian Institute of Company Directors and was the former Managing Director and Chief Executive Officer of IM Medical Ltd., an ASX-listed company committed to the use of innovative technology to promote health and well being.



# Quarterly Activities Report for the guarter ended 31 December 2009

### **CORPORATE MATTERS (cont.)**

On 17 December 2009, the Company announced that it had executed an exclusive option to evaluate the purchase of the BREVAGen breast cancer diagnostic product from Perlegen Sciences Inc. of Mountain View, California, USA. The BREVAGen test is a diagnostic product that informs clinicians and patients about individual, non-familial, sporadic risk of breast cancer for women who have undergone biopsies where the outcome is indeterminate. Approximately 1.6 million women undergo breast biopsies annually in the US and 65%, or 1 million, of these are indeterminate. If acquired, the BREVAGen product will build further upon Genetic Technologies' strategy to provide the most advanced and comprehensive products in the cancer management area. The Company is currently undertaking due diligence investigations in respect of the potential transaction which, should it proceed, will consist of an asset purchase rather than a corporate acquisition. The rights to be acquired will be global and will include the purchase of laboratory equipment, intellectual property, certifications, sales and marketing material and other trade secrets and know-how.

Signed on behalf of Genetic Technologies Limited				
DR. PAUL D.R. MacLEMAN	Dated this 29 <sup>th</sup> day of January, 2010			
DR. PAUL D.R. MacLEMAN Chief Executive Officer	Dated this 29 <sup>th</sup> day of January, 2010			

 $Rule\ 4.7B$ 

# **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

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17 009 212 328

Quarter ended ("current quarter")

**31 DECEMBER 2009** 

#### Consolidated statement of cash flows

			Current quarter (December 2009) \$A	Year to date (six months) \$A
	Cash flows rel	ated to operating activities		
1.1	Receipts from	customers	2,708,914	4,674,334
1.2	Payments for	(a) staff costs	(1,715,767)	(3,391,900)
		(b) advertising and marketing	(91,381)	(155,578)
		(c) research and development	(47,517)	(137,622)
		(d) leased assets	-	-
		(e) other working capital	(2,127,909)	(3,984,396)
1.3	Dividends rece	ived	-	-
1.4	Interest and items of a similar nature received		59,201	128,536
1.5	Interest and other costs of finance paid		(23,765)	(48,055)
1.6	Income taxes paid		-	-
1.7	Grant and other	rincome	-	572,128
	Net operating	cash flows	(1,238,224)	(2,342,553)

<sup>+</sup> See chapter 19 for defined terms.

## Consolidated statement of cash flows (cont.)

		Current quarter (December 2009) \$A	Year to date (six months) \$A
1.8	Net operating cash flows (carried forward)	(1,238,224)	(2,342,553)
	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  e) other non-current assets	- - (80,810) (9,897)	- - (98,868) (9,897)
1.10	Proceeds from the disposal of:  a) businesses (item 5)  b) equity investments  c) intellectual property  d) physical non-current assets  e) joint venture interest	- 295,195 - - -	- 295,195 - -
1.11	Loans to other entities	-	-
1.12	Loans repaid by other entities	-	-
1.13	Other (provide details if material)	-	-
	Net investing cash flows	204,488	186,430
1.14	Total operating and investing cash flows	(1,033,736)	(2,156,123)
	Cash flows related to financing activities		
1.15	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	(62,963)	(110,613)
	Net financing cash flows	(62,963)	(110,613)
	Net increase / (decrease) in cash held	(1,096,699)	(2,266,736)
1.21	Cash at beginning of quarter / year to date	6,635,695	7,826,902
1.22	Exchange rate adjustments	20,670	(500)
1.23	Cash at end of quarter	5,559,666	5,559,666

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<sup>+</sup> 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	184,993
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 \$59,202 paid in consulting fees, bonuses, commissions, Directors' fees, superannuation and salaries to Directors and entities associated with Directors during the quarter. The amount also includes rental and outgoings of \$125,791 for the Melbourne laboratory premises paid to an entity associated with a former Director.

#### 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			

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

#### 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	497,432

<sup>+</sup> See chapter 19 for defined terms.

#### **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:		Current quarter (December 2009) \$A	Previous quarter (September 2009) \$A
4.1	Cash on hand and at bank	2,559,666	2,617,708
4.2	Term deposits	3,000,000	4,017,987
4.3	Bank overdraft	-	-
4.4	Commercial Bills of Exchange	-	-
	Total cash at end of quarter (item 1.23)	5,559,666	6,635,695

## Acquisitions and disposals of business entities

		Acquisitions (Item $1.9(a)$ )	Disposals (Item 1.10(a))
5.1	Name of entity	Not applicable	Not applicable
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		

#### **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: 29 January 2010

Chief Executive Officer

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

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<sup>+</sup> 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.

<sup>+</sup> See chapter 19 for defined terms.