

Total equity	5,758,287	14,402,642	6,813,995	5,717,696	14,112,045
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Exchange rates

The following table sets forth, for the periods and dates indicated, certain information concerning the noon buying rate in New York City for Australian dollars expressed in U.S. dollars per \$1.00 as certified for customs purposes by the Federal Reserve Bank of New York.

Period ended	At period end	Average rate	High	Low
Yearly data				
June 2009	0.8055	0.7513	0.9797	0.6073
June 2010	0.8480	0.8820	0.9369	0.7751
June 2011	1.0732	0.9905	1.0732	0.8380
June 2012	1.0236	1.0323	1.1026	0.9453
June 2013	0.9165	1.0272	1.0591	0.9165
Monthly data				
June 2013	0.9165	0.9440	0.9770	0.9165
July 2013	0.8957	0.9155	0.9259	0.8957
August 2013	0.8901	0.9037	0.9193	0.8901
September 2013	0.9342	0.9303	0.9444	0.9055
October 2013 (note)	0.9671	0.9477	0.9671	0.9366

Note: Data for the month of October 2013 covers the period from October 1, 2013 to October 18, 2013.

Item 3.B Capitalization and Indebtedness

Not applicable.

Item 3.C Reasons for the Offer and Use of Proceeds

Not applicable.

Item 3.D Risk Factors

Before you purchase our ADSs, you should be aware that there are risks, including those described below. You should consider carefully these risk factors together with all of the other information contained elsewhere in this Annual Report before you decide to purchase our ADSs.

Risks Related to Us

Our stock price is volatile and can fluctuate significantly based on events not in our control and general industry conditions. As a result, the value of your investment may decline significantly.

The biotechnology sector can be particularly vulnerable to abrupt changes in investor sentiment. Stock prices of companies in the biotechnology industry, including ours, can swing dramatically, with little relationship to operating performance. Our stock price may be affected by a number of factors including, but not limited to:

- product development events;
- the outcome of litigation;
- decisions relating to intellectual property rights;
- the entrance of competitive products or technologies into our markets;
- new medical discoveries;
- the establishment of strategic partnerships and alliances;
- changes in reimbursement policies or other practices related to the pharmaceutical industry; or
- other industry and market changes or trends.

Since our listing on the Australian Securities Exchange in August 2000, the price of our Ordinary Shares has ranged from a low of \$0.02 to a high of \$1.05 per share. Further fluctuations are likely to occur due to events which are not within our control and general market conditions affecting the biotechnology sector or the stock market generally.

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In addition, low trading volume may increase the volatility of the price of our ADSs. A thin trading market could cause the price of our ADSs to fluctuate significantly more than the stock market as a whole. For example, trades involving a relatively small number of our ADSs may have a greater impact on the trading price for our ADSs than would be the case if the trading volume were higher.

The following chart illustrates the fluctuation in the price of our shares (in Australian dollars) over the last five years:



The fact that we do not expect to pay cash dividends may lead to decreased prices for our stock.

We have never paid a cash dividend on our Ordinary Shares and we do not anticipate paying a cash dividend in the foreseeable future. We intend to retain future cash earnings, if any, for reinvestment in the development and expansion of our business. Whether we pay cash dividends in the future will be at the discretion of our Board of directors and may be dependent on our financial condition, results of operations, capital requirements and any other factors our Board of directors decides is relevant. As a result, an investor may only recognize an economic gain on an investment in our stock from an appreciation in the price of our stock.

You may have difficulty in effecting service of legal process and enforcing judgments against us and our Management.

We are a public company limited by shares, registered and operating under the Australian *Corporations Act 2001*. The majority of our directors and officers named in this Annual Report reside outside the U.S. Substantially all, or a substantial portion of, the assets of those persons are also located outside the U.S. As a result, it may not be possible to affect service on such persons in the U.S. or to enforce, in foreign courts, judgments against such persons obtained in U.S. courts and predicated on the civil liability provisions of the federal securities laws of the U.S. Furthermore, substantially all of our directly-owned assets are located outside the U.S., and, as such, any judgment obtained in the U.S. against us may not be collectible within the U.S. There is doubt as to the enforceability in the Commonwealth of Australia, in original actions or in actions for enforcement of judgments of U.S. courts, of civil liabilities predicated solely upon federal or state securities laws of the U.S., especially in the case of enforcement of judgments of U.S. courts where the defendant has not been properly served in Australia.

Because we are not necessarily required to provide you with the same information as an issuer of securities based in the United States, you may not be afforded the same protection or information you would have if you had invested in a public corporation based in the United States.

We are exempt from certain provisions of the Securities Exchange Act of 1934, as amended, commonly referred to as the Exchange Act, that are applicable to U.S. public companies, including (i) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current reports on Form 8-K; (ii) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; and (iii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time. The exempt provisions would be available to you if you had invested in a U.S. corporation.

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However, in line with the Australian Securities Exchange regulations, we disclose our financial results on a semi-annual basis which are required to have a limited review semi-annually and to be fully audited annually. The information, which may have an effect on our stock price on the Australian Securities Exchange, will also be disclosed to the Australian Securities Exchange and the Securities Exchange Commission. Other relevant information pertaining to our Company will also be disclosed in line with the Australian Securities Exchange regulations and information dissemination requirements for listed companies. We will provide our semi-annual results and other material information that we make public in Australia in the U.S. under the cover of an SEC Form 6-K. Nevertheless, you may not be afforded the same protection or information, which would be made available to you, were you investing in a United States public corporation because the requirements of a Form 10-Q and Form 8-K are not applicable to us.

If significant liquidity does not eventuate for our ADSs on NASDAQ, your ability to resell your ADSs could be negatively affected because there would be limited buyers for your interests.

Historically, there was virtually no trading in our ADSs through the pink sheets after the establishment of our Level I ADR Program. However, subsequent to the Level II listing of our ADSs on the NASDAQ Global Market on September 2, 2005, the trading volumes of our ADSs have increased. The Company subsequently transferred the listing of its ADSs to the NASDAQ Capital Market effective as from June 30, 2010. An active trading market for the ADSs, however, may not be maintained in the future. If an active trading market is not maintained, the liquidity and trading prices of the ADSs could be negatively affected.

In certain circumstances, holders of ADRs may have limited rights relative to holders of Ordinary Shares.

The rights of holders of ADSs with respect to the voting of Ordinary Shares and the right to receive certain distributions may be limited in certain respects by the deposit agreement entered into by us and The Bank of New York Mellon. For example, although ADS holders are entitled under the deposit agreement, subject to any applicable provisions of Australian law and of our Constitution, to instruct the depositary as to the exercise of the voting rights pertaining to the Ordinary Shares represented by the American Depositary Shares, and the depositary has agreed that it will try, as far as practical, to vote the Ordinary Shares so represented in accordance with such instructions, ADS holders may not receive notices sent by the depositary in time to ensure that the depositary will vote the Ordinary Shares. This means that, from a practical point of view, the holders of ADRs may not be able to exercise their right to vote. In addition, under the deposit agreement, the depositary has the right to restrict distributions to holders of the ADSs in the event that it is unlawful or impractical to make such distributions. We have no obligation to take any action to permit distributions to holders of our American Depositary Receipts, or ADRs. As a result, holders of ADRs may not receive distributions made by us.

Our Company has a history of incurring losses.

The business now called Genetic Technologies Limited was founded in 1989. Up until the year ended June 30, 2011, we have incurred operating losses in every year of our existence. We incurred net losses of \$7,841,073 for year ended June 30, 2009, net losses of \$9,343,766 for year ended June 30, 2010, a net profit of \$910,002 for year ended June 30, 2011, net losses of \$5,287,523 for year ended June 30, 2012 and net losses of \$9,298,367 for year ended June 30, 2013. As of June 30, 2013, we have accumulated losses of \$82,049,916 and the extent of any future losses and whether or not the Company can generate profits remains uncertain.

Risks Related to our Industry

Our sales cycle is typically lengthy.

The sales cycle for our testing products and license generation is typically lengthy. As a result, we may expend substantial funds and management effort with no assurance of successfully selling our products or services or granting new licenses. Our ability to obtain customers for our genetic testing services depends significantly on the perception that our services can help accelerate efforts in genomics. Our sales effort requires the effective demonstration of the benefits of our services to, and significant training of, many different departments within a potential customer. In addition, we sometimes are required to negotiate agreements containing terms unique to each customer. With respect to license generation, it is common for negotiations with licensees to take many months before a license is eventually granted. Our business could also be adversely affected if we expend money without any return.

If our competitors develop superior products, our operations and financial condition could be affected.

We are currently subject to limited competition from biotechnology and diagnostic companies, academic and research institutions and government or other publicly-funded agencies that are pursuing products and services which are substantially similar to our genetic testing services, or which otherwise address the needs of our customers and potential customers. Our competitors in the testing market include private and public sector enterprises located in Australia, the U.S. and elsewhere. Many of the organizations competing with us have greater experience in the areas of finance, research and development, manufacturing, marketing, sales, distribution, technical and regulatory matters than we do. In addition, many current and potential competitors have greater name / brand recognition and more extensive collaborative relationships. However, because of our patents, we have virtually no competition in the licensing area.

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Our competitive position in the genetic testing area is based upon, amongst other things, our ability to:

- create and maintain scientifically-advanced technology and offer proprietary products and services;
- attract and retain qualified personnel;
- obtain patent or other protection for our products and services;
- obtain required government approvals and other accreditations on a timely basis; and
- successfully market our products and services.

If we are not successful in meeting these goals, our business could be adversely affected. Similarly, our competitors may succeed in developing technologies, products or services that are more effective than any that we are developing or that would render our technology and services obsolete, noncompetitive or uneconomical.

For a full discussion of competition see Item 4.B "Competition".

We rely heavily upon our patents and proprietary technology and any future claims that our patents are invalid could seriously affect our licensing business and adversely affect our revenues and our financial condition.

We rely upon our portfolio of patent rights, patent applications and exclusive licenses to patents and patent applications relating to genetic technologies. We expect to aggressively patent and protect our proprietary technologies. However, we cannot be certain that any additional patents will be issued to us as a result of our domestic or foreign patent applications or that any of our patents will withstand challenges by others. Patents issued to, or licensed by, us may be infringed or third parties may independently develop the same or similar technologies. Similarly, our patents may not provide us with meaningful protection from competitors, including those who may pursue patents which may prevent, limit or interfere with our products or will require licensing and the payment of significant fees or royalties by us to such third parties in order to enable us to conduct our business. We may sue or be sued by third parties regarding our patents and other intellectual property rights. These suits are often costly and would divert valuable funds and technical resources from our operations and cause distraction to Management.

We have important relationships with external parties over whom we have limited control.

We have relationships with academic consultants and other advisers who are not employed by us. Accordingly, we have limited control over their activities and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results of operations. To the extent that our scientific consultants develop inventions or processes independently that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to such information, and we may not win those disputes.

If we are unable to protect our proprietary assets, we may not be able to commercialize products or services.

Our commercial success partially depends on our ability to obtain patent protection for many aspects of our business, including the products, methods and services we develop. Patents issued to us may not provide us with substantial protection or be commercially beneficial to us. The issuance of a patent is not conclusive as to its validity or its enforceability. In addition, our patent applications or those we have licensed, may not result in issued patents. If our patent applications do not result in issued patents, our competitors may obtain rights to commercialize our discoveries which could harm our competitive position. We also may apply for patent protection on novel genetic variations in known genes and their uses, as well as novel uses for previously identified genetic variations discovered by third parties. In the latter cases, we may need a license from the holder of the patent with respect to such genetic variations in order to make, use or sell any related products. We may not be able to acquire such licenses on terms acceptable to us, if at all.

Certain parties are attempting to rapidly identify and characterize genes and genetic variations through the use of sequencing and other technologies. To the extent that any patents are issued to other parties on such partial or full-length genes or genetic variations or uses for such genes or genetic variations, the risk increases that the sale of products or services developed by us or our collaborators may give rise to claims of patent infringement against us. Others may have filed and, in the future, are likely to file patent applications covering many genetic variations and their uses. Any such

patent applications may have priority over our patent applications and could further require us to obtain rights to previously issued patents covering genetic variations. Any license that we may require under any such patent may not be made available to us on commercially acceptable terms, if at all.

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We may be sued for infringing on the intellectual property rights of others. We could also become involved in interference proceedings in the United States Patent and Trademark Office to determine the relative priority of our patents or patent applications and those of the other parties involved in the interference proceeding. Intellectual property proceedings are costly, and could affect our results of operations. These proceedings can also divert the attention of managerial and technical personnel. If we do not prevail in any intellectual property proceeding, in addition to any damages we might have to pay, we could be required to stop the infringing activity, or obtain a license to or design around the intellectual property in question. In interference proceedings, our patent rights could be invalidated and the scope of our patents could be limited. If we are unable to obtain licenses to intellectual property rights that we need to conduct our business, or are unable to design around any third party patent, we may be unable to sell some of our products, which will result in reduced revenue.

We have in the past and may in the future become a party to litigation involving patents and intellectual property rights. We have previously commenced litigation against a number of parties to protect our rights pertaining to our intellectual property. We may in the future receive claims of infringement of intellectual property rights from other parties. If we do not prevail in any future legal proceedings, we may be required to pay significant monetary damages. In addition, we could also be prevented from using certain processes or prevented from selling certain configurations of our products or services that were found to be within the scope of the patent claims. In the event we did not prevail in any future proceeding, we would either have to obtain licenses from the other party, avoid certain product configurations or modify some of our products, services and processes to design around the patents. Licenses could be costly or unavailable on commercially reasonable terms. Designing around patents or focusing efforts on different configurations could be time consuming, and we may have to remove some of our products or services from the market while we were completing redesigns. Accordingly, if we are unable to settle future intellectual property disputes through licensing or similar arrangements, or if any such future disputes are determined adversely to us, our ability to market and sell our products and services could be harmed. This would in turn reduce demands for our services and harm our financial condition and results of operations.

In addition, in order to protect or enforce our patent rights or to protect our ability to operate our business, we may need to initiate other patent litigation against third parties. These lawsuits could be expensive, take significant time to resolve, and could divert Management's attention from other business concerns. These lawsuits could result in the invalidation or limitation in the scope of our patents or forfeiture of the rights associated with our patents. We may not prevail in any such proceedings and a court may find damages or award other remedies in favor of our opposing party in any of these suits. During the course of any future proceedings, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. Securities analysts or investors may perceive these announcements to be negative, which could cause the market price of our stock to decline.

We may be subject to professional liability suits and our insurance may not be sufficient to cover damages. If this occurs, our business and financial condition may be adversely affected.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of genetic tests. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to professional liability claims and possible adverse publicity. We may be subject to claims resulting from incorrect results of analysis of genetic variations or other screening tests performed using our services. Litigation of such claims could be costly. We could expend significant funds during any litigation proceeding brought against us. Further, if a court were to require us to pay damages to a plaintiff, the amount of such damages could significantly harm our financial condition. Although we have public and product liability insurance coverage under broadform liability and professional indemnity policies, for an aggregate amount of \$60,000,000, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. To date we have not been subject to any claims, or ultimately liability, in excess of the amount of our coverage. In addition, we may not be able to obtain additional professional liability coverage in the future at an acceptable cost. A successful claim or series of claims brought against us in excess of our insurance coverage and the effect of professional liability litigation upon the reputation and marketability of our technology and products, together with the diversion of the attention of key personnel, could negatively affect our business.

We use potentially hazardous materials, chemicals and patient samples in our business and any disputes relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development, production and service activities involve the controlled use of hazardous laboratory materials and chemicals, including small quantities of acid and alcohol, and patient tissue and blood samples. We do not knowingly deal with infectious samples. We, our collaborators and service providers are subject to stringent Australian federal, state and local laws and regulations governing occupational health and safety standards, including those governing the use, storage, handling and disposal of these materials and certain waste products. However, we could be liable for accidental contamination or discharge or any resultant injury from hazardous materials, and conveyance, processing, and storage of and data on patient samples. If we, our collaborators or service providers fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. Further, future changes to environmental health and safety laws could cause us to incur additional expense or restrict our operations. We have never had a reportable serious injury through the date of this Annual Report.

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In addition, our collaborators and service providers may be working with these types of hazardous materials, including hazardous chemicals, in connection with our collaborations. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these patient samples that may contain viruses and hazardous materials. The cost of this liability could exceed our resources. While we maintain broadform liability insurance coverage for these risks, in the amount of up to \$40,000,000, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. To date, we have not been subject to claims, or ultimately liability, in excess of the amount of our coverage. Our broadform insurance coverage also covers us against losses arising from an interruption of our business activities as a result of the mishandling of such materials. We also maintain workers' compensation insurance, which is mandatory in Australia, covering all of our workers in the event of injury.

We depend on the collaborative efforts of our academic and corporate partners for research, development and commercialization of some of our products. A breach by our partners of their obligations, or the termination of the relationship, could deprive us of valuable resources and require additional investment of time and money.

Our strategy for research, development and commercialization of some of our products has historically involved entering into various arrangements with academic and corporate partners and others. As a result, our strategy depends, in part, upon the success of these outside parties in performing their responsibilities. Our collaborators may also be our competitors. We cannot necessarily control the amount and timing of resources that our collaborators devote to performing their contractual obligations and we have no certainty that these parties will perform their obligations as expected or that any revenue will be derived from these arrangements.

If our collaborators breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities in a timely manner, the development or commercialization of the product candidate or research program under such collaborative arrangement may be delayed. If that is the case, we may be required to undertake unforeseen additional responsibilities or to devote unforeseen additional funds or other resources to such development or commercialization, or such development or commercialization could be terminated. The termination or cancellation of collaborative arrangements could adversely affect our financial condition, intellectual property position and general operations. In addition, disagreements between collaborators and us could lead to delays in the collaborative research, development, or commercialization of certain products or could require or result in formal legal process or arbitration for resolution. These consequences could be time-consuming and expensive and could have material adverse effects on us.

Other than our contractual rights under our license agreements, we may be limited in our ability to convince our licensees to fulfill their obligations. If our licensees fail to act promptly and effectively, or if a dispute arises, it could have a material adverse effect on our results of operations and the price of our Ordinary Shares and ADSs.

We rely upon scientific, technical and clinical data supplied by academic and corporate collaborators, licensors, licensees, independent contractors and others in the evaluation and development of potential therapeutic methods. There may be errors or omissions in this data that would materially adversely affect the development of these methods.

We may seek additional collaborative arrangements to develop and commercialize our products in the future. We may not be able to negotiate acceptable arrangements in the future and, if negotiated, we have no certainty that they will be on favorable terms or if they will be successful. In addition, our partners may pursue alternative technologies independently or in collaboration with others as a means of developing treatments for the diseases targeted by their collaborative programs with us. If any of these events occurs, the progress of the Company could be adversely affected and our results of operations and financial condition could suffer.

Problems associated with international business operations could affect our ability to license our technology and our results of operations.

We seek to license our intellectual property and to market our growing range of other products and services on a global scale, including in countries that are considered to provide significantly less protection to intellectual property than the United States and Australia. In addition, a number of other risks are inherent in international transactions and commerce, including political and economic instability, foreign currency exchange fluctuations and changes in tax laws.

Government regulation of genetic research or testing may adversely affect the demand for our services and impair our business and operations.

Apart from accreditation requirements, we are generally not subject to regulation. From time to time, federal, state and/or local governments adopt regulations relating to the conduct of genetic research and genetic testing. In future, these regulations could limit or restrict genetic research activities as well as genetic testing for research or clinical purposes. In addition, if such regulations are adopted, these regulations may be inconsistent with, or in conflict with, regulations adopted by other government bodies. Regulations relating to genetic research activities could adversely affect our ability to conduct our research and development activities. Regulations restricting genetic testing could adversely affect our ability to market and sell our products and services. Accordingly, any regulations of this nature could increase the costs of our operations or restrict our ability to conduct our testing business and might adversely affect our operations and financial condition.

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Gene Patenting Debate in Australia

In 2008, the Australian Senate commenced an inquiry into the issues surrounding the patenting of genes. The inquiry was due to report its findings in early 2009. On September 30, 2010, the Senate re-referred the matter to the Senate Community Affairs Committee for inquiry and report. Having extended the timeline on several occasions, the Senate inquiry was then interrupted by an Australian Federal election in October 2010.

On November 26, 2010, the report arising from the Senate's inquiry into gene patents was released. It tabled 16 recommendations primarily aimed at making amendments to existing provisions of the Patents Act, while minimizing unforeseen consequences of changes to biotechnology sector, including the potential prohibition on patenting biological materials.

The Senate Report also noted a number of events that may affect further decisions, such as the Private Member's Bill that was introduced into the Federal Parliament. The Private Member's Bill was referred immediately to the Legal and Constitutional Affairs - Legislation Committee for inquiry and report by June 16, 2011. The Report also said "... the Committee heard conflicting evidence as to whether a prohibition on the patenting of genes and other biological materials (a) would be effective, and (b) would not lead to unforeseen consequences in other fields of technology, particularly biotechnology, research and development."

The *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the "Bill") was introduced in the Lower House of the Australian Parliament on October 18, 2010. On November 26, 2010, the Senate referred the Bill to the Legal and Constitutional Affairs - Legislation Committee. The Committee received 122 submissions and held two public hearings for inquiry where 31 witnesses appeared at the public hearings. On September 22, 2011, the report arising from the Senate's inquiry into the Bill was released. It tabled only one recommendation: "The Committee recommends that the Senate should not pass the Bill."

The *Intellectual Property Laws Amendment (Raising the Bar) Bill 2012* was passed into law on March 20, 2012. This legislation does not ban or restrict patents on genetic material other than by "raising the bar" for the granting of any new patents.

Australian Federal Court Patent Proceeding

In June 2010, a group of Australian plaintiffs initiated litigation in the Australian Federal Court challenging the validity of certain claims of an Australian patent owned by Myriad Genetics Inc. (Australian patent 686004 - "'004"). Genetic Technologies was named as a respondent to this matter by virtue of the fact that Genetic Technologies is the exclusive licensee of the BRCA patents in Australia (which includes the '004 patent).

This matter bears a resemblance to the U.S. litigation filed by the American Civil Liberties Union against Myriad's U.S. patent equivalent in which a U.S. Federal District Court ruled that isolated DNA sequences are not eligible for patent protection because of the fact that they are "products of nature". On July 29, 2011, Myriad successfully appealed this decision with the Federal Circuit Court of Appeals reversing the decision of the United States District Court for the Southern District of New York. On March 26, 2012 the U.S. Supreme Court remanded the case back to the U.S. Court of Appeals for the Federal Circuit for reconsideration. On August 16, 2012, the U.S. Court of Appeals for the Federal Circuit ruled on the Myriad case in the U.S., upholding the patentability of gene patents. In a further development in the case of the Association for Molecular Pathology v. Myriad Genetics, on June 13, 2013, the Supreme Court ruled (1) that isolated genomic DNA (gDNA) is not patentable under section 101 of the Patent Act, but (2) cDNA (which the Court defined as "synthetically created DNA") is patentable. The decision was intended to provide some clarity around DNA patents, but appears to have had the opposite effect and caused further uncertainty which is likely to persist for the foreseeable future.

On September 30, 2011, Genetic Technologies filed documents with the Australian Federal Court to the effect that the Company submits to the orders of the Court and takes no further part in the proceedings. On February 15, 2013, the Australian Federal Court ruled in favor of Myriad Genetics in this matter.

Myriad Genetics argued that by virtue of the process of extracting the gene from the body, it had satisfied the requirements of an "invention" according to section 18(1)(a) of the Patents Act which states that an invention must be a "manner of manufacture". Based on previous case law, the Court held that a "manner of manufacture" requires an "artificial state of affairs" of some discernible effect that is of economic significance.

That decision was subsequently appealed by one of the plaintiffs on March 4, 2013 and that appeal has been heard by the courts and a judgment is due in the near future, making the impact of the trial decision uncertain at this stage.

We rely on the services of individuals who possess special skills and experience.

Much of the future success of the Company depends on the continued service and availability of skilled personnel, including members of its senior executive team, and those in technical, marketing and staff positions. While we actively recruit new employees with such skills and experience to reduce our reliance on these individuals, skilled personnel, with specific experience in the biotechnology industry, are in high demand and competition for their talents is intense.

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Ethical and other concerns surrounding the use of genetic information may reduce the demand for our services.

Public opinion regarding ethical issues related to the confidentiality and appropriate use of genetic testing results may influence government authorities to call for limits on, or regulation of the use of, genetic testing. In addition, such authorities could prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Furthermore, adverse publicity or public opinion relating to genetic research and testing, even in the absence of any governmental regulation, could reduce the potential markets for our services, which could materially and adversely affect our revenues.

Although we are a leader in the field of genetics in Australia, we do not undertake any activities in the contentious areas of cloning, stem cell research or other gene-altering areas. As such, many of the ethical issues that may be relevant to other participants in the genetics industry are not necessarily applicable to us.

Out-licensing of our intellectual property

The patenting of genes and issues surrounding access to genetic knowledge are the subjects of extensive and ongoing public debate in many countries. By way of example, the Australian Law Reform Commission has previously conducted two inquiries into the social uses of genetic information. The patents we hold over uses of "non-coding" DNA have broad scope and have also been the subject of debate and some criticism in the media. A risk we face is that individuals or organizations in one or more of the countries in which these patents have issued could take legal action to seek their amendment, revocation or invalidation, something which has happened previously on several occasions in various jurisdictions, though we have prevailed in all such cases.

Furthermore, any time that we initiate legal action against parties that infringe our patents we face a risk that the infringer will defend itself through a counter-claim of patent invalidity or other such claims. Subsequent legal action could potentially overturn, invalidate or limit the scope of our patents.

Under the relevant Patent Acts in most of the countries in which our non-coding patents have issued, the relevant judicial system has rights to impose compulsory licensing. The relevant governments typically hold "march-in" rights by which they may unilaterally choose to exploit the technology. To the extent that the Company's non-coding technology is used in the conduct of research, we also face risks, uncertainty and controversy over the licensing of our technology to those conducting research. Whether or not researchers should be exempted from obligations to take licenses to relevant patents was the subject of another government inquiry conducted by the Australian Council for Intellectual Property who recommended the creation of a research exemption.

For further information relevant to this subject, refer to the section entitled *Gene Patenting Debate in Australia* earlier in this section 3.D.

Our genetic testing activities

There is a view held by some elements of the medical and academic communities that the marketing of some of our cancer predisposition and risk assessment tests is done solely with a commercial objective in mind. In essence, some parties have indicated that, in their view, the risk of inheriting certain types of cancer is too low to warrant the marketing of genetic testing services to the wider cancer community where such promotion may increase anxiety unnecessarily. Guidelines laid down by the Australian National Health Medical Research Council also prevent us from promoting our testing in a manner which may "cause any unnecessary alarm".

In recent years, health care payers as well as federal and state governments have focused on containing or reducing health care costs. We cannot predict the effect that any of these initiatives may have on our business. In particular, gene-based therapeutics, if successfully developed and commercialized, are likely to be costly compared to currently available drug therapies. Health care cost containment initiatives focused either on gene-based therapeutics or on genetic testing could result in the growth in the clinical market for genetic testing being curtailed or slowed. In addition, health care cost containment initiatives could also cause pharmaceutical companies to reduce research and development spending. In either case, our business and our operating results could be adversely affected. Further, genetic testing in clinical settings is often billed to third-party payers, including private insurers and governmental organizations. If our current and future clinical products and services are not considered cost-effective by these payers, reimbursement may not be available to users of our services. In this event, potential customers would be much less likely to use our services and our business and operating results could be harmed. Further, the amounts we receive in respect of the tests we perform may fall.