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TroVax

Global development and commercialisation deal with sanofi-aventis



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BUSINESS REVIEW STRATEGY

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Key Performance Indicators

Our goal is to create a profitable biopharmaceutical company through the commercialisation of novel safe and effective gene-based medicines to treat unmet medical needs. To mitigate the inherent risks of drug development, we have adopted a hybrid business model that combines in-house and collaborative research and development, enabling us to establish a portfolio of product candidates that address multiple therapeutic areas. We also actively out-license our proprietary technologies for use in research or drug development to generate near-term revenue streams and, in some cases, royalties on product sales. In 2007, we undertook a review of our pipeline to prioritise our development efforts and maximise the potential return from our in-house investment. With rigorous financial management, we aim to deliver sustained growth and value for our shareholders and other stakeholders.

Our corporate strategy is defined by six core strategic themes. These themes are consistent with our near and long-term objectives for the business, and we have adopted them as Key Performance Indicators to measure our progress. Our six themes are as follows:

1. Focus on advancing key development programmes, which offer the greatest commercial value
2. Broaden the technology platform and out-license technologies for near-term revenue
3. Expand the clinical pipeline by at least one new product per year
4. Partner certain products with companies for late-stage development
5. Retain commercial rights for certain products to maximise value
6. Maintain effective management of financial and human resources

In this section, we describe the relevance of these themes to our corporate strategy, assess our performance in 2007, and set out our targets for 2008.

FOCUS ON ADVANCING KEY DEVELOPMENT PROGRAMMES

Link to Strategy: In 2007, we conducted a review of our pipeline to assess the return on investment for each product candidate, by considering the commercial opportunity based on the anticipated competitive profile, together with timelines and costs of development. We are now focusing our internal resources on those product candidates that offer the greatest potential value.

Performance: Our focus in 2007 has been on progressing TroVax through Phase III development in renal cancer, advancing ProSavin into a Phase I/II trial in Parkinson's disease, and preparing for the clinical development of RetinoStat in wet age-related macular degeneration. We also initiated a new anti-cancer programme, EndoAngio-GT, which is designed to block blood vessel growth (angiogenesis) in tumours. This mechanism of action has been proven in various preclinical models of solid tumours and confirmed in clinical studies with monoclonal antibodies targeting tumour vessel growth. The development of EndoAngio-GT is expected to benefit from synergies with RetinoStat.

Targets: Our development priorities in 2008 are unchanged. We will continue to manage the Phase III TRIST study of TroVax, while sanofi-aventis takes responsibility for Phase III development in colorectal cancer. For ProSavin, in addition to the ongoing Phase I/II trial, we are preparing for the next stage of the product's development, which could be a Phase III trial. We are continuing our preparations for clinical trials of RetinoStat.

BROADEN TECHNOLOGY PLATFORM

Link to Strategy: Intellectual property (IP) is essential to our success. It provides us with freedom to operate and protects our products from competition, enhancing their commercial value. We aim to be the leading company in our fields of gene-based medicines and immunotherapy with a toolbox of technologies, such that we can apply the most appropriate gene delivery system for any therapeutic gene, mechanism of action or target tissue. By out-licensing our technologies, we also generate near-term revenue and build commercial relationships that may become more valuable in the future.

Performance: In January 2008, we secured exclusive rights to use our LentiVector technology in the field of RNA interference (gene silencing), which is a targeted therapeutic approach that has many applications and is attracting substantial investment. In March 2007, we acquired Oxxon Therapeutics, which has strengthened our proprietary position in immunotherapy. Sigma-Aldrich is our strategic partner for the commercialisation of LentiVector-based reagents for use in research. We receive royalties on sales of these reagents. During 2007 Sigma-Aldrich expanded its product range. In 2007, Oxford BioMedica and Sigma-Aldrich also licensed the LentiVector technology to another major US-based biotechnology company for use in its in-house research activities.

Targets: We are evaluating various opportunities to in-license or acquire technology that complements our existing IP and can generate both near and long-term value. During 2008, we plan to exploit our rights in RNA interference through partnerships and also new in-house programmes.

EXPAND CLINICAL PIPELINE

Link to Strategy: Our success will ultimately come from commercialisation of novel, safe and effective therapies that utilise our proprietary technologies, whether developed by Oxford BioMedica or our partners. Broadening our clinical pipeline with additional product candidates increases our commercial potential and also reduces development risk through diversification.

Performance: In 2007, we added two programmes to our clinical pipeline. Firstly, through Oxxon Therapeutics, we acquired a therapeutic vaccine for melanoma, Hi-8 MEL, which is in Phase II development. Secondly, in December 2007, we received clearance from the regulatory authorities to start the Phase I/II trial of ProSavin in Parkinson's disease. This is the first product

to enter clinical development that uses our LentiVector technology.

Targets: We are preparing for a submission to start clinical trials of RetinoStat for the treatment of wet age-related macular degeneration. We expect this to happen in 2009. We have several further preclinical candidates that could enter the clinic in the next two years, including EndoAngio-GT for cancer and StarGen for Stargardt's disease.

PARTNER CERTAIN PRODUCTS

Link to Strategy: Our product candidates are principally designed for use in hospital settings and specialist centres. Some hospital products require competitive marketing and substantial investment in commercial infrastructure. Based on our current resources, our strategy is to seek partners for these types of products to access additional capabilities for product development and commercialisation. In addition, following the strategic review of our pipeline, we are seeking suitable partners for our non-priority product candidates to ensure that they are developed and commercialised to their full potential.

Performance: In 2007, our licensing deal with sanofi-aventis for TroVax was a major achievement. The development of TroVax will require substantial investment over the next few years. Similarly, its commercialisation will benefit from an established sales and marketing infrastructure, particularly if the product has proven application in multiple settings and cancer types. Sanofi-aventis is an ideal partner for TroVax, given its global capabilities and existing oncology franchise.

Targets: In our strategic review, we identified certain non-priority product candidates, which we intend to partner for further development. These include MetXia, which is a localised therapy for accessible tumours, that could be developed to treat pancreatic, breast and prostate cancer and also glioma (brain cancer).

RETAIN RIGHTS FOR CERTAIN PRODUCTS

Link to Strategy: The most successful biotech companies are fully integrated, which means that they develop and market their own products. By following this model in niche markets that require small but specialised sales forces, we can capture more value from the commercialisation of our innovative products with limited investment.

Performance: In 2007, we conducted a risk-reward assessment of the ProSavin programme and concluded that there was a strong rationale to retain commercialisation rights in certain territories and establish a specialised neurological sales and marketing infrastructure. Furthermore, in our alliance with sanofi-aventis, we have retained an option to participate in the promotion of TroVax in the USA and EU, which would enable us to establish an oncology franchise.

Targets: We are evaluating various strategies for the development of ProSavin, which would provide additional finance and resource, thus reducing the financial risk for Oxford BioMedica, while allowing us to retain commercialisation rights. For ProSavin and some of our preclinical product candidates, we aim to progress discussions with potential partners in territories that are outside of our core focus, during 2008.

MAINTAIN EFFECTIVE MANAGEMENT

Link to Strategy: Our continued growth requires ongoing investment in our pipeline and technologies. We also need to recruit and retain key people with relevant skills and training for our in-house activities. We aim to keep our fixed costs to a minimum by using outsourced service providers where appropriate. To ensure that our business is sustainable during our pre-commercialisation



RetinoStat & StarGen

Preclinical data presented at ARVO meeting

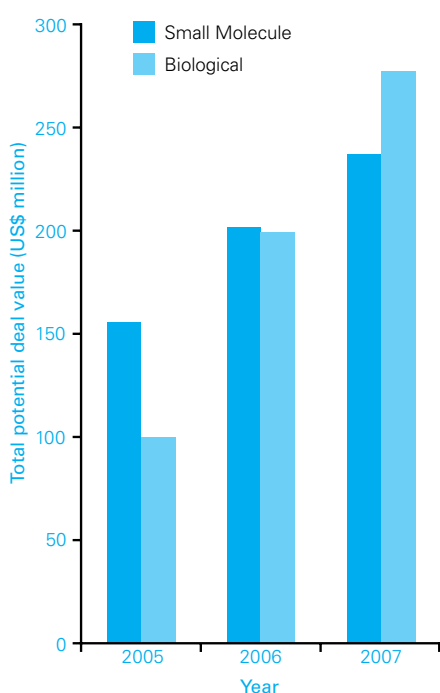
phase, we maintain a principle of having financial resources for a minimum operational period of 12 months.

Performance: We have established a solid track record of meeting or beating our financial targets in recent years. In 2007, we have strengthened our cash position and have sufficient resources for our ongoing operations. During the year we conducted a strategic review of our development pipeline to enable us to focus investment on opportunities that could generate the greatest value.

Targets: We will continue to monitor the investment requirements for each of our programmes and will expand our internal operations as required to meet our objectives. Our financial goal is to be profitable within 12 months of registration of our first product, which could be in 2009 following a successful outcome from the Phase III TRIST study of TroVax in renal cancer.

Markets

Average deal values for small molecule and biologic deals. (PharmaDeals, 2008)



2007 could be described as the year that the pharmaceutical industry reinforced its long-term commitment to the development and commercialisation of novel biological therapies and technologies. The acquisition of the US biotechnology company MedImmune by AstraZeneca was one of the largest ever biotech deals, and followed AstraZeneca's previous buyout and integration of Cambridge Antibody Technology in the UK. Pfizer, Novartis and Roche are investing in new or enhanced biotechnology units with increased budgets for the discovery and development of novel biologics. Potentially more relevant to Oxford BioMedica, was an announcement by our partner for TroVax, sanofi-aventis, of its goal to boost sales from biologics to up to 30% of total sales in five years from about 10% today.

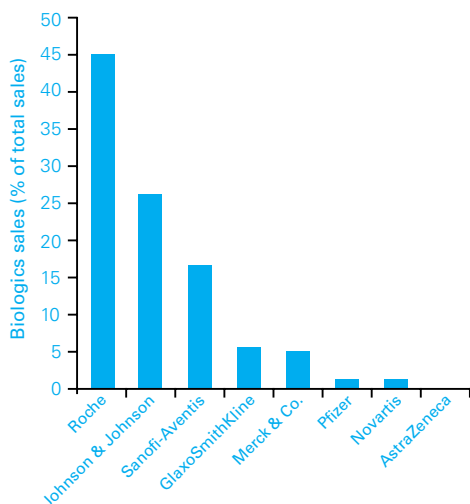
to lose another US\$12 billion in 2007, according to IMS Health. Biotechnology drugs face less competition from generic versions because their complexity raises the clinical and regulatory requirements for approval of "biogenerics" and their manufacturing requires substantial investment and infrastructure.

Within the multiple sub-sectors of biotechnology, Oxford BioMedica is focused on gene therapy and cancer immunotherapy.

GENE THERAPY AND CANCER IMMUNOTHERAPY

Gene therapy is 'the treatment or prevention of disease by gene transfer' and involves the genetic modification of human cells by introducing one or more genes. This approach is most obviously associated with replacing missing or defective genes, through the introduction of a normal working version of the gene. However, the field has its greatest potential in providing endogenous factories of pharmacologically active molecules that cannot be administered by conventional means. This is our approach with ProSavin, which delivers genes for synthesising dopamine for treatment of Parkinson's disease. Furthermore, gene-based approaches can be used to activate the immune system to kill disease cells. Our lead product, TroVax, delivers a gene that produces a protein found on cancer cells in a fashion that enables this to be recognised as foreign by the patient's immune system. The patient's immune system then attacks and kills cancer cells that express the protein.

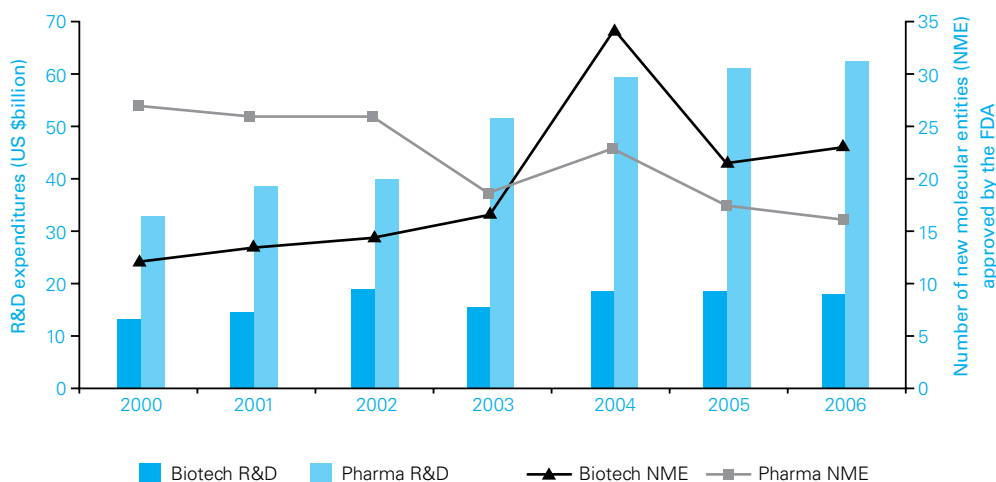
Proportion of biologics sales by big pharma in 2006 (Pharma Deals; Evaluate Pharma, 2008)



Biotechnology drugs, which can be defined simply as drugs derived from living cell cultures instead of traditional chemistry, are an attractive investment for two basic reasons: the industry is fast-growing and generic competition is limited.

- The biotechnology industry is expanding much more rapidly than traditional pharmaceuticals. Biotech sales in the USA grew 20% to US\$40.3 billion in 2006, while pharmaceutical sales grew 8% to US\$275 billion, according to IMS Health.
- Biotechnology drugs are less vulnerable to generic competition upon patent expirations, which is the main concern of the pharmaceutical industry. The pharmaceutical industry lost US\$14 billion worth of annual drug sales to patent expirations in 2006 and was expected

Biotech and big pharma R&D expenditures vs approvals (Ernst & Young, 2007)



DELIVERY SYSTEM IS KEY

There is no perfect delivery system that can be used to treat every disorder. Like any type of medical treatment, a delivery system must be customised to address the unique features of the disorder and choosing the most suitable vector is part of the challenge in gene therapy. Factors that influence the selection of the delivery system include the target cell type and whether these have been removed from the body (*ex vivo*) or are still in the body (*in vivo*), the duration of gene expression required for therapeutic effect, and the size of the piece of DNA to be used in the gene therapy.

Viral vectors are widely used for gene delivery since they have a natural ability to enter a cell and deliver genetic material both efficiently and in a defined manner. Oxford BioMedica's proprietary LentiVector system is based on highly engineered lentiviruses. Unlike some other commonly used viral vectors, the LentiVector technology has the ability to integrate genes into the genome of non-dividing cells as well as dividing cells. The breadth of our LentiVector-based pipeline reflects the utility of the technology. It has potential application in the treatment of neurological disorders (e.g. ProSavin for Parkinson's disease), eye diseases (e.g. RetinoStat for wet age-related macular degeneration), genetic diseases, chronic infections and also cancer.

Our cancer immunotherapy programmes utilise a Modified Vaccinia Ankara (MVA) virus, which is an attenuated form of vaccinia. MVA is an effective vector system for delivering and inducing an immune response against recombinant tumour antigens. The vector itself has an excellent safety profile and

was used widely some years ago as a vaccine for the eradication of smallpox and more recently for biodefence stockpiling.

SAFETY CONCERNS

Regulatory authorities in the USA and EU have yet to approve a human gene therapy for sale. There have been some notable clinical successes with gene therapy in various disease settings. However, the critics of gene therapy have always focused on the handful of adverse events that have occurred in some of these trials, although none of these have been with Oxford BioMedica's products or vector systems.

In 1999, gene therapy suffered its first major setback with the death of 18-year-old Jesse Gelsinger. Mr Gelsinger was participating in a gene therapy trial and his death is believed to have been triggered by a severe immune response to the adenoviral vector being evaluated.

Another issue arose in 2003 when the FDA placed a temporary halt on all gene therapy trials using retroviral vectors in blood stem cells. The FDA took this action after two children treated in a French gene therapy trial developed a leukaemia-like condition. On analysis, it was concluded that these events were primarily driven by the trial design and nature of the therapeutic gene and not a broader issue related to gene therapy *per se*. Less media coverage was given to the fact that most patients were successfully treated by this potentially life-saving gene therapy for X-linked severe combined immunodeficiency disease (X-SCID), also known as 'bubble boy syndrome' where no alternative treatments exist.

More recently, in 2007, a patient died following treatment in a trial of an adeno-associated virus-based product for inflammatory arthritis in the USA. The FDA suspended the trial but then lifted its hold after its safety review indicated that the product did not contribute to the patient's death. Very few pharmaceuticals or biopharmaceuticals have zero risk and gene therapy is no exception.

It is worth stressing that Oxford BioMedica's LentiVector technology and the MVA system in our cancer immunotherapies have not been associated with any serious safety issues. However, these previous incidents reinforce the need for rigorous safety testing of our gene-based products.

REGULATORY PROGRESS

A new regulatory process for the approval of advanced products, including gene therapies, in the EU came in to force on 30 December 2007. The regulation on advanced therapy medicinal products offers a framework to support the advancement of these products with access to scientific advice and a centralised European approval process. For Oxford BioMedica, the new regulation provides greater clarity on the route to market in Europe for our product candidates, and potentially reduces clinical timelines and regulatory uncertainty.

In 2007, for the first time, an advisory panel of the US FDA assessed a therapeutic cancer vaccine. The product in question was Dendreon's prostate cancer vaccine, Provenge. The panel was unanimous that a safety claim could be supported and voted 13-4 that there was substantial evidence of efficacy based on a secondary endpoint of median survival.

Testimony from patients and patient advocacy groups also appeared to influence the FDA panel in light of the toxicity associated with other existing treatments. There was a very strong appeal for the approval of a product that could provide a better quality of life with a good safety profile, even if it conferred only a slight extension on life.

The supportive sentiment of the advisory panel is a landmark event for the field of cancer vaccines, although the FDA subsequently issued an “approvable letter” requesting additional clinical data. It indicates that the FDA’s advisory committee has adopted a pragmatic and flexible approach to this new treatment paradigm and is an encouraging sign for the field of cancer vaccines including TroVax.

China is the first country to have a commercial gene therapy. The Chinese biotechnology company, Shenzhen SiBiono GenTech, received approval from the State Food and Drug Administration of China for its anti-cancer product, Gendicine, for the treatment of head and neck cancer in 2003. Gendicine uses an adenoviral vector to deliver the gene for p53. The success of Gendicine can only help Oxford BioMedica and the field of gene therapy gain global acceptance.

RNA INTERFERENCE

In January 2008, Oxford BioMedica entered the field of RNA interference (RNAi) based therapeutics through a licensing agreement that provides rights to key Nobel Prize-winning RNAi patents. There has been substantial investment in the therapeutic application of RNAi in the last few years.

For example, Merck & Co acquired the US RNAi company Sirna for US\$1.1 billion, closing the transaction in early 2007, and there have been several large pharma-biotech collaborations in the field.

ADDRESSING LONG-TERM DELIVERY

Traditionally, gene therapy has focused on supplying a normal copy of a faulty or absent gene, whereas RNAi turns off a problematic gene. In fact, these contrasting approaches share some of the same challenges, principally the delivery of the therapeutic gene or siRNA into cells. For many diseases, particularly genetic and chronic disorders, the success of RNAi therapies will depend upon efficient long-term delivery of the intermediates of RNAi, particularly short interfering RNA (siRNA). Oxford BioMedica’s LentiVector technology provides an ideal solution for long-term delivery of siRNA. Several pharmaceutical companies, such as GlaxoSmithKline, Merck & Co and Pfizer, are already using our system for targeted delivery of siRNA in their research activities, under technology licensing agreements. With rights for therapeutic RNAi applications, we are evaluating in-house and collaborative opportunities.

Principal Risks and Uncertainties

Risk assessment and evaluation is an integral part of our planning. Most of the risks and uncertainties that we face are common to all development-stage biopharmaceutical companies. Where possible, our strategy is designed to manage and mitigate these issues. Our principal risks and the uncertainties, particularly as they relate to the next few years, are described below.

INTELLECTUAL PROPERTY AND PATENT PROTECTION RISK

Our commercial success will depend, amongst other things, on maintaining proprietary rights to our products and technologies. There can be no assurance that our products and technologies are adequately protected by intellectual property. If proceedings are initiated against our patents, the defence of such rights could involve substantial costs and an uncertain outcome. Third-party patents may emerge containing claims that impact our freedom to operate. There can be no assurance that we will be able to obtain licences to these patents at reasonable cost, if at all, or be able to develop or obtain alternative technology. The Board of Oxford BioMedica gives high priority to the strategic management of the Company's intellectual property portfolio and we actively monitor the competitive environment. As well as protection of our products and technologies, we use our intellectual property estate to generate value through out-licensing activities.

DEVELOPMENT RISK

Safety or efficacy issues may arise at any stage of the drug development process. Adverse or inconclusive results from preclinical testing or clinical trials may substantially delay, or halt, the development of our product candidates, consequently affecting our timelines for profitability. Results of the TRIST study and the other planned Phase III trials may differ from those obtained in previous clinical trials and additional data may be required for regulatory approval. Similarly, the results of our preclinical studies with ProSavin and RetinoStat may not be reproduced in human clinical trials.

REGULATORY REVIEW RISK

Our products will be subject to the regulatory review and approval process by agencies across the world to assess their safety, efficacy and manufacture, amongst other aspects. There can be no assurance that our products will successfully gain the necessary regulatory approvals for launch. The time taken to obtain regulatory approval varies between territories and while some agencies, like the US FDA, have pre-defined review periods, others are less predictable. Furthermore, each regulatory authority may impose its own restrictions on the product label, or may require additional data before granting an approval. In the case of TroVax, sanofi-aventis has global responsibility for the regulatory process and the programme remains on-track for the first regulatory submission and review in 2009.

COLLABORATION AND THIRD-PARTY RISK

Our current and future revenue is dependent on the successful outcome of a number of collaborations. Our most important alliances are with sanofi-aventis, Wyeth and Sigma-Aldrich. In addition, we have collaborations with other companies relating to products and technologies, as well as agreements with contract organisations for preclinical and clinical testing and manufacturing. There can be no assurance that these relationships will be successful and they may be terminated or require re-negotiation. Circumstances may also arise where the failure by collaborators and third parties to perform their obligations in accordance with our agreements could delay, or halt entirely, the evaluation, development, production or commercialisation of our products and technologies. Such events could adversely affect our existing and anticipated revenue streams.

PHARMACEUTICAL PRICING RISK

The ability of Oxford BioMedica and our partners to commercialise our products may depend on the extent to which reimbursement will be available from government health administration authorities, private health coverage insurers and other organisations. There is no assurance that adequate health administration or third-party re-imbursment will be available or that

Hi-8 MEL

Encouraging results from Phase II trials of Hi-8 MEL presented at American Association of Immunologists Meeting



satisfactory price levels will be reached. In addition, there is increasing pressure in many territories to contain healthcare costs by limiting both coverage and the level of reimbursement. Increasingly, new therapeutic products are being assessed on the basis of their cost effectiveness. TroVax is being evaluated in Phase III trials in combination with standard therapy. As an add-on to existing treatment, we will need to justify its cost effectiveness in order to secure suitable pricing and reimbursement.

COMPETITION RISK

Our competitors, and potential competitors, include some of the major pharmaceutical and biotechnology companies, many of whom have substantially greater resources than us. Our products are potentially "best in class" candidates and, in the case of TroVax, we are collaborating with a major company in oncology and vaccines. However, there can be no assurance that competitors will not succeed in developing products and technologies that are more effective or economic than ours, which, in the worst case, could render our products and technologies obsolete or otherwise uncompetitive.

FINANCIAL RISK

We expect to record a net cash outflow from operations in 2008 as we continue to invest in our research and development efforts, taking into account milestone payments from sanofi-aventis and our other licensing income. We have sufficient working capital for our current operating activities until the end of 2009, excluding future milestone

payments from sanofi-aventis. Our capital requirements after that date, if any, depend on the achievement of TroVax-related milestones and securing new collaborations. The first regulatory submission of the product in renal cancer, which is anticipated in 2009 in the USA, triggers a significant milestone payment. However, there is the risk that we may have to increase the follow-up duration of the Phase III TRIST study, which would delay the timing of this payment. Similarly, the achievement of these regulatory milestone events depends on various factors, some of which are outside our control, the most important determinant being the outcome of the Phase III TRIST study.

STAFF RISK

While we have employment contracts with all of our personnel, the retention of their services cannot be guaranteed. Recruiting and retaining key management and scientific personnel as we build the business will be critical to our success.

GENE THERAPY RISK

There are no gene therapies approved for sale in the USA or EU. The commercial success of gene-based medicines such as ours will depend, in part, on acceptance by the medical community and the public. Furthermore, specific regulatory requirements, over and above those imposed on pharmaceutical products generally, apply to gene therapy and there can be no assurance that further additional requirements will not be imposed in the future as a result of new concerns. This may increase the cost and time necessary

for development of our products. However, there have been some recent developments relating to cancer vaccines and gene-based medicines that suggest the regulatory authorities in the USA and EU are supportive of these novel treatment approaches. These are described in the Markets section of the Business Review on pages 16 to 18.

