HOW TO MAKE QLT A TOP TEN BIOTECHNOLOGY COMPANY: STRATEGIC ANALYSIS OF GROWTH OPPORTUNITIES

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ABSTRACT

QLT's vision is to become a top ten biotechnology company by 2010. We analyze QLT's growth strategy within the context of the biotechnology industry and QLT's internal environment, and suggest growth objectives and strategies to achieve a top ten ranking. QLT's current projected growth rate is short of achieving this goal; QLT needs to increase its annualized average growth rate to 37%, revenues to $700 million and profits to $220 million by 2010. To achieve these targets QLT needs a broader development pipeline and more diversified commercial revenues, which can be accomplished by adding sales capabilities, and expanding the product pipeline and revenue potential through product in-licensing or partnering, and mergers and acquisitions with companies such as Ligand Pharmaceuticals. QLT should also build its core capabilities in innovative drug delivery platforms and focus on markets with high unmet medical needs to build a higher profile in the biotechnology industry.

EXECUTIVE SUMMARY

Success within the biotechnology industry requires a high degree of innovation with a solid scientific basis, strong knowledge of the regulatory processes, high tolerance for risk, and ready access to large amounts of capital. QLT Inc. has succeeded thus far in becoming one of the few profitable companies in the industry worldwide; it has fulfilled these challenging criteria and achieved commercial success with its major product, Visudyne®. To further build upon this success and consolidate its position in the industry, QLT has developed an ambitious corporate vision of becoming a top ten biotechnology company worldwide by market capitalization by 2010. This paper analyzes the industry forces and QLT's internal environment in order to recommend specific growth objectives and strategies to help achieve this vision.

QLT Inc. is at a challenging crossroads in its corporate development. The company has successfully developed and commercialized several products, and has a number of candidates in its product pipeline. QLT recently merged with Atrix Laboratories to create a U.S. subsidiary and increase its commercial and pipeline potential, as well as build on the company's core capabilities in drug delivery and combination products. However, the company is dependent on a number of marketing partners for the sale and distribution of its commercial products, which limits its revenues and future growth potential. An analysis of the industry leaders shows that all of these companies are fully integrated along the drug development value chain, highlighting the importance of adopting this business model to succeed in the industry.

Growth Objectives

In reviewing the financial parameters and valuations of the current top ten biotechnology companies, we found on average much higher estimated growth rates and price to earnings ratios compared to QLT's position. The top ten companies also have a broader range of commercial products and larger development pipelines. To rank among this top tier, we determined the following financial objectives for QLT by 2010 (all U.S. dollars):

- Target market capitalization of $10 billion (Currently $1.1 billion).

- Annualized average growth rate of 37% (Current estimate 20-25%).
- Revenues over $700 million (revenues were $186 million in 2004).
- Profits of $220 million (profits were $57 million in 2004).
- Price to earnings ratio of 58 (Currently 21).

Recommended Growth Strategies

To achieve these growth objectives, QLT needs to add commercial sales capability to extract more value from its products. Adding commercial sales capability will also allow QLT to acquire commercial rights to additional high potential products that can drive revenue and income growth. The current development pipeline should be supplemented with 3 to 4 products in mid to late-stage clinical development with medium to high market potential, which can be acquired through mergers and acquisitions, in-licensing, or strategic alliance. In addition, QLT needs to develop a stronger corporate brand and higher profile in the industry by building on its core capabilities in drug development and combination products. This will in turn give QLT unique positioning among the leading biotechnology companies and facilitate negotiations of business development deals with favourable terms. QLT should also build capabilities in emerging areas of biotechnology, such as genomics and personalized medicine, through strategic acquisition of new technology platforms to enhance its capabilities in advanced drug delivery systems.

Mergers and acquisitions (M&A) can be challenging to execute, but offer the best potential for QLT to meet its growth objectives. QLT should focus its M&A efforts on companies with good fit in the following major areas: therapeutic area compatibility, product and pipeline potential, sales capability, near and long-term financial advantage, innovation, ability to enter new markets, and management compatibility. Using these parameters, we screened potential M&A candidates in the biotechnology industry with a market capitalization between $100 million and $1.5 billion, and did a detailed deal evaluation on the following five most promising companies: Connetics Corporation, Ligand Pharmaceuticals, Cell Therapeutics, Barrier Therapeutics, and Cell Genesys. From this group, Ligand Pharmaceuticals offers the best fit to QLT's growth requirements, and we recommend that QLT consider a merger of equals with this company following further preliminary investigation.

DEDICATION

We thank our families and friends for their support throughout the program and this project.

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1 INTRODUCTION AND BACKGROUND

QLT Inc is a Vancouver based biopharmaceutical company whose vision is "to be among the top ten biotechnology companies worldwide in terms of market capitalization by 2010" (QLT Inc., 2004, April 2). Given that it is currently ranked 30th with a market capitalization of $1.1 billion (Yahoo! Finance, 2005, January 29), approximately four times less than the tenth-ranked biotechnology company Celgene ($4.7 billion; Yahoo! Finance, 2005, January 29), this is a very ambitious goal. Strong growth strategies and careful planning and implementation will be essential to achieving this goal. The growth strategy will need to consider the potential of the company's current commercial and pipeline products, its core capabilities, and the appropriate business model to drive rapid and sustainable growth.

Many biotechnology companies have developed lucrative drugs, but very few have leveraged these products into long-term profitability and growth. The market leaders in the industry have all had multiple successful product launches. The first few products were usually launched with a pharmaceutical partner to take advantage of their marketing experience, then profits from the early products were used to fund later pipeline development and build in-house sales and marketing capabilities. QLT is at a challenging crossroads in its corporate development: the company has had a successful product launch with Visudyne®, is in the process of building its markets with another product Eligard®, and has a third product, Aczone™, nearing commercialization. However, the company has partnered all of these products with larger pharmaceutical companies, and has yet to retain the rights to commercialize a product on its own. In order to compete with the market leading biotechnology companies, the company may need to make this transition and become a vertically integrated company by incorporating sales and marketing capabilities, or it may need to find some other method of creating sustainable competitive advantage and growth potential that will attract investors and drive the optimal valuation that it seeks.

1.1 Objective and Scope of Analysis

The objective of this paper is to carry out an analysis of QLT Inc.'s corporate strategy from a business development perspective, and suggest the growth strategies that will help QLT

achieve its vision. The framework for this strategic evaluation will consist of three main analyses: 1) an analysis of the biotechnology industry, in particular the business models of the market leaders and major trends and opportunities from the external environment; 2) an evaluation of QLT's internal environment, in particular its therapeutic focus and product pipeline using a growth matrix; and 3) an evaluation of QLT's valuation, core capabilities and business model in comparison to market leaders.

From these analyses, we will outline the recommended growth strategies for QLT, including the appropriate business model that will maximize growth potential while taking into consideration QLT's core capabilities. While we will look at QLT's product mix and pipeline in enough detail to determine its potential to drive QLT's valuation growth, we will maintain a high level, corporate overview of strategic directions, rather than a product or market based strategic view. We will also set the target valuation for the company for 2010 and determine the growth rate that the company will need to achieve to reach this valuation in the required timeframe. We will then outline an action plan that addresses the next steps needed to achieve rapid growth as well as addressing any gaps in the company's capabilities that may hinder its ability to reach its growth target and sustainable competitive advantage in the industry.

1.2 Report Structure

Chapter 1 of this paper presents the background of QLT Inc., the company's recent merger with Atrix Laboratories, and a summary of the current areas of business.

Chapter 2 provides an analysis of the biotechnology industry in which QLT operates, with an overview of the drug development business, and an analysis of the biotechnology industry in general along with some of the trends and opportunities in the sector using the PESTEL framework. We also analyze the business models of some of the market leaders in the biotechnology and specialty pharmaceutical sector. As a basis for further comparison with QLT and to determine an appropriate target valuation and growth rate for the company, we provide an analysis of the business valuations of these market leaders.

In chapter 3, we provide an in-depth analysis of QLT's internal environment to determine the company's current business model, growth strategy, product potential, and capabilities. We use this analysis to determine the gaps in QLT's growth potential and capabilities. We also carry out a stakeholder analysis as a basis for our recommendations on how to achieve buy-in for our recommended business development opportunities.

Our analysis of optimal growth strategies based on the industry and internal environment is presented in chapter 4. We present appropriate growth objectives for QLT, including target growth rates in income and revenues, and a target valuation. We also outline the business strategy that we believe will enable the company to achieve these objectives, and examine the internal and external opportunities for business development. We provide an in-depth evaluation of potential candidates for near term business development deals that support QLT's business model and growth objectives.

Chapter 5 presents in-depth recommendations and action plan for growth. We prioritize the potential business development deals and provide a recommendation to QLT's senior management as to which deals to pursue. For the recommended deal, we present a preliminary strategy for realizing the deal. We also provide an action plan and financial strategy for all of the recommended next steps for QLT to pursue to meet the company's growth objectives. We discuss how our assumptions influence our strategic recommendations and outline some alternatives to consider if these assumptions change. Finally, we provide recommendations for additional follow-up research and strategic analysis that QLT should carry out in order to achieve its growth objectives.

1.3 QLT Inc. Background and History

Founded in 1981, QLT Inc. is a Vancouver, British Columbia (BC) based biopharmaceutical company focused on treatments for cancer, eye diseases, and dermatological and urological conditions (QLT Inc., 2004, September). QLT was formed by a collaboration of scientists, led by QLT's founder Dr. Julia Levy, who researched photosensitizers at the University of British Columbia. Photosensitizers, or light activated drugs, are administered intravenously, locally by injection or topically to preferentially accumulate in target tissue. When these drugs come in contact with light at a specific wavelength generated by a device, they are activated and destroy abnormal cells or tissue.

QLT went public in 1986 and raised $3 million through an initial public offering on the Vancouver Stock Exchange (QLT Inc., 2004, September). In 1987, QLT entered an alliance with American Cyanamid and raised $15 million to develop the world's first approved photodynamic therapy (PDT) (GCS Research Society, 2001). Up to 1999, QLT raised a total of $386.5 million through seven follow-on rounds of financing (QLT Inc., 2004, September). The first generation PDT product was Photofrin® to treat cancer, and this was sold to Axcan Pharma Inc. in 2000

(QLT Inc., 2004, April). Visudyne®, the second generation PDT, is for the treatment of wet age related macular degeneration (AMD) and is approved in 70 countries. Dr. Julia Levy first heard of the disease when her mother was diagnosed with wet AMD, the leading cause of blindness in people over 55, and was inspired to put together the photodynamic treatment for the condition (GCS Research Society, 2001). QLT's third generation PDT is lemuteporfin, and the company is currently conducting clinical trials for the treatment of benign prostatic hyperplasia (BPH).

In order to commercialize Visudyne®, QLT formed a second strategic alliance in 1994 with Ciba Vision, now Novartis Ophthalmics (QLT Inc., 2004, September). The agreement included shared development costs (60:40 Novartis:QLT) and a 50:50 profit split, with QLT in charge of manufacturing and Novartis leading the commercialization efforts. This partnership was strategic for QLT because the company took the lead in strategic planning, opinion leader development and reimbursement strategies (QLT Inc., 2004, September).

Today, QLT has become a pioneer and world leader in PDT (QLT Inc., 2004, September). The QLT motto is "Our Business is Science, Our Product is Life". QLT has 150,000 square feet of "state of the art" laboratories at their Headquarters in Vancouver. The company employs over 450 staff and was ranked 28th out of 50 in the "The Best Employers in Canada, 2005" list (QLT Inc., 2004, September). QLT is an ethically and socially responsible company, committed to providing its patients with high standard care and its employees with a rich environment. The company provides grants for programs related to QLT's research activities in ophthalmology, oncology, dermatology and urology, and sponsors research that furthers science education in BC and betters the community in which QLT is located (QLT Inc., 2005, February 16). Primary among these is a 5 year collaborative research program that provides $3.4 million in funding along with the National Science and Engineering Research Council of Canada to develop new photosensitizers with photodynamic therapy pioneer, Professor David Dolphin of the University of British Columbia (University of British Columbia, 2000).

The senior management of QLT is headed by Paul Hastings, who has been the President and Chief Executive Officer (CEO) since 2002, when Dr. Levy retired from this position. Paul Hastings has had extensive experience in the drug development business, starting in sales at Hoffman La Roche, and built extensive leadership experience at a number of well-known biotechnology companies, including Genzyme, Chiron, and most recently at Axys Pharmaceuticals, where he orchestrated an acquisition by Celera Genomics (QLT Inc., 2005,

February 14). He is successful at a young age for a CEO, at only 45 in March 2005, and is committed to living in Vancouver and making a long term career at the helm of QLT.

1.4 Merger with Atrix

In November 2004, QLT Inc. merged with biopharmaceutical company Atrix Laboratories Inc. of Fort Collins, U.S.A., which has become a subsidiary of QLT Inc. called QLT USA Inc. QLT USA adds approximately 179 employees to the company, and brings a commercially proven drug delivery platform and expertise to the combined company. The merger required payment of $338 million in cash to Atrix shareholders and the issue of 23.2 million additional common shares by QLT Inc. (QLT Inc., 2004, October 19).

The main reasons for QLT Inc. executing the merger with Atrix are to provide the following (QLT Inc., 2004, October 19):

- Growing product portfolio and immediate diversification of revenues
- Expansion of the near and mid-term pipeline
- Validated drug delivery platforms and technologies
- Sufficient financial resources to achieve strategic objectives and have an appropriate earnings profile
- Combination of core human resource competencies to yield a more full-integrated and competitive biopharmaceutical company

This merger follows a trend in the biotechnology industry towards an increasing number of mergers and alliances. In 2003 alone, there were 91 mergers between biotechnology companies, up from 20 in 1996 (Robinson, 2003). Mergers tend to occur between larger companies that are anticipating gaps in their pipeline, and smaller companies that are in financial trouble (Danzon, Epstein and Nicholson, 2004). The merger between QLT and Atrix fits this profile: QLT had a limited pipeline of products and a large reserve of cash in early 2004, whereas Atrix had a relatively robust late stage pipeline but negative earnings and limited cash to continue developing its pipeline.

In this paper, the name QLT or QLT Inc. will be used to refer to the combined entity of the original QLT Inc. and QLT USA unless otherwise noted. All figures throughout this paper are quoted in US dollars because this is primary currency in which the company operates.

1.5 Current Areas of Business

The combined company is in the business of drug development and commercialization, with a focus on innovative products and advanced drug delivery technologies and platforms, including photodynamic therapy, Atrigel® and SMP™. QLT's stated business strategy is "to pursue expanded indications for Visudyne® therapy and develop and commercialize other products with particular focus on the fields of ophthalmology, oncology, and dermatology" (QLT Inc., 2004, March 12). QLT is profitable and currently has a number of commercial products on the market including products for eye disease, dermatology, cancer, and dentistry, which will be detailed in chapter 3.

QLT also has a number of products in various stages of development in ophthalmology, oncology, dermatology, and urology. In addition to its clinical development programs, QLT has a research group which is focused on the preclinical stage of drug development and is actively working on expanding its product pipeline internally. The focus of the preclinical research is similar to the commercial and development focus, namely to develop new therapies for eye disease, cancer, dermatology, and urology using the company's drug delivery and formulation expertise. In addition to this internal research, the company also has the objective of growing its pipeline through strategic acquisitions or in-licensing.

While the company has been successful in developing products from discovery and research through clinical development, the regulatory approval process, and manufacturing, QLT does not yet have a commercial marketing and sales force to promote and distribute these products. QLT relies on a number of marketing partners, mainly large pharmaceutical companies with established sales forces, for commercialization of its products.

2 INDUSTRY ANALYSIS

This chapter describes the business of drug development and analyzes the biotechnology industry as a background for the strategic analysis of QLT. To conduct the biotechnology industry analysis, we use the PESTEL strategic analysis framework. A PESTEL analysis involves reviewing the political, economic, social, technological, environmental, and legal factors that influence an industry. These are the main factors in the macro-environment for an industry, and can determine the opportunities and threats in the strategic direction of the industry that a company needs to take into account when determining their own corporate strategies. Later in the chapter, we also examine the business models and valuations of some of the market leaders in this industry as a basis for comparison with QLT.

2.1 Drug Development Business

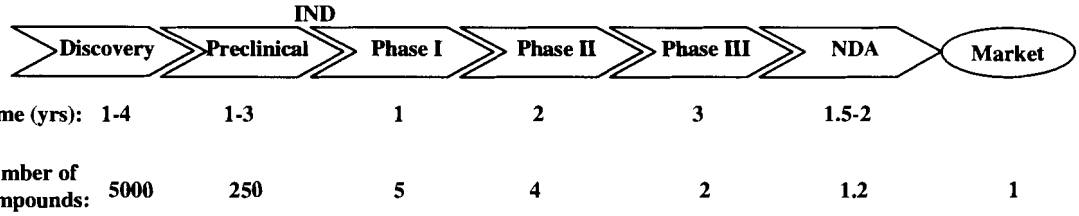
Drug development is a subset of the health care business, involving the process of research, development, and commercialization of medical therapies for use in treatment of human medical conditions. The products of this process are the prescription drugs used by health care practitioners, usually physicians, in a variety of medical categories known as therapeutic areas, such as dermatology, cardiovascular disease, cancer (oncology), etc. There are currently two major industries involved in the drug development business: the pharmaceutical industry, and the newer biotechnology industry. These two industries are differentiated on the basis of their technology platforms: pharmaceutical companies were founded upon their expertise in the chemical synthesis of small molecule therapies and their marketing expertise, whereas biotechnology is based upon biologically based, large molecule drugs or novel technology platforms. The line between these two industries has blurred in recent years, as pharmaceutical companies acquire biotechnology expertise and use molecular targets and techniques, and biotechnology companies gain marketing and sales expertise, as well as developing small molecule drugs when appropriate. The industries are now mainly differentiated on the basis of company-defined strategic focus and core capabilities. Because QLT defines itself through competition in the biotechnology sector, our focus in this paper will be on the biotechnology industry.

2.1.1 Development and Approval Process

Drug development is a business that is regulated by government authorities in most parts of the world. Prescription drugs intended for use as human therapeutics must go through a rigorous testing process to demonstrate safety and efficacy prior to regulatory approval to market the product. The major regulatory authorities are the Food and Drug Administration (FDA) in the United States, the EMEA (European Commission) in Europe, and the HFPB (Health and Food Protection Branch) in Canada. These agencies are responsible for assessing new drug products and for approving or rejecting them for marketing and use in humans. Because the United States is considered to be the largest market for drugs, this paper will generally focus on the development process in the U.S. and the FDA requirements for approval.

Drug development spans the range from discovery research through preclinical and clinical testing, and the regulatory steps. Figure 1 shows the major stages of the drug development process. Discovery involves biological or disease target selection, and can take many years to produce a worthwhile target for further preclinical testing. The preclinical stage includes research resulting in proof of concept and lead compound selection from in vitro and animal testing, and formal preclinical development to satisfy regulatory requirements for demonstration of safety and efficacy in animals before proceeding to human testing.

Figure 1 New Drug Development Process



Source: Based on information in DiMasi (1995), Centre for Medicines Research International (2004) and Pharmaceutical Research and Manufacturers of America (2004, January)

Once the preclinical development is complete, a company files an Investigational New Drug application (IND) to receive approval for testing a compound in humans. Once this approval is received, a compound can proceed to the three phases of clinical testing. Phase I clinical trials generally involve testing for safety in 20-80 healthy volunteers. Phase II involves initial testing of efficacy and further safety in a larger number of patients, typically 100-300. Phase III clinical trials are also known as pivotal trials, and involve testing in a broad patient

population, often 1000-3000 people, which is a time-consuming and expensive endeavour. Once the clinical testing is completed, companies must prepare a comprehensive regulatory package, known as a New Drug Application (NDA) in the U.S., to request approval to market the product. The preparation of the package often takes half a year or more, and the review by the FDA can take 1 to 2 years on average (Pharmaceutical Research and Manufacturers of America, 2004, January).

Parallel to the preclinical and clinical testing is extensive manufacturing development. Companies must scale an initial product formulation from laboratory scale up to commercial scale by the time the NDA is submitted, and this manufacturing process is governed by stringent regulatory requirements for process and product validation to ensure consistency and quality of the product.

2.1.2 Risks, Timelines, and Costs

Drug development is a high risk, costly, and lengthy process. The probability of success for any new drug product is extremely low, with industry estimates that for every 10,000 compounds that are tested in the preclinical research phase, only 1 will enter the market (Figure 1). The average success rate at each stage of clinical drug development is: Phase I 20%, Phase II 25%, Phase III 60% and NDA 90% (CMR, 2004). The main reasons for failure of drugs are problems with efficacy (33-38%), economics (30-34%), and safety (20%) (DiMasi, 2001).

Bringing a new drug product to market takes between 10 and 15 years and costs $800 million (Pharmaceutical Research and Manufacturers of America, 2004, March), when the cost of failed products and overhead is included. The cost of bringing any one successful product from preclinical research through to marketing approval can range from $20-120 million depending on the disease, not including the capital costs for buildings, major equipment, and administrative or senior management overhead. The most expensive stages of drug development are typically the human clinical trials and manufacturing process development. As an industry, pharmaceutical and biotechnology companies spent a combined $33.2 billion on research and development of new drugs in 2003 (Pharmaceutical Research and Manufacturers of America, 2004, March). Despite these enormous expenditures, only 3 out of 10 marketed drugs bring in revenues that recover the cost of development (Pharmaceutical Research and Manufacturers of America, 2005).

In addition to these high costs and long development timelines, recent problems with some commercial products such as the COX-2 inhibitors are likely to make the FDA more

conservative about clinical development plans and endpoints, which may force longer clinical trials with larger patient populations. In September 2004, Merck withdrew their popular pain medication, Vioxx®, from the market due to concerns about increased risk of heart problems from long-term use after carrying out post-marketing approval studies (Merck & Co., Inc., 2004). Following this news, there has been much public discussion about the safety of other COX-2 inhibitors, and the FDA has come under intense scrutiny and criticism for its role in approving COX-2 drugs and for being slow in responding to reports of side effects from approved drugs (Reuters, 2005). The implications for drug approvals are that the FDA may become more risk-averse, taking longer to review and approve drugs (The Economist, 2004) and requiring more clinical data on safety and efficacy prior to approval.

Drug development companies can work to reduce these timelines, risks, and costs by adopting innovative research and development (R&D) strategies that improve success rates for clinical trials and reduce the costs of these studies. Key measures for companies to adopt include terminating development of unpromising products earlier in the process, using better preclinical screening methods and modeling techniques, and reducing the length of clinical trials by using tools such as surrogate endpoints (DiMasi, 2002). Because of the uncertainty with FDA's risk tolerance following the COX-2 issues described above, companies may be more successful in reducing the time spent on discovery and research, prior to the FDA's involvement.

2.1.3 Commercialization

Once a product receives marketing approval from the regulatory agencies, it can be commercially launched. Because of the segmentation of the health care market into different medical specialties, known as therapeutic areas, specialized sales forces are necessary to successfully market a new product. While the segmented nature means that there are often well-defined physician or health care provider markets, which limit the size of the sales force needed, these are knowledge-driven markets and require highly trained and knowledgeable sales forces across large geographic areas. Hiring, training, and maintaining these sales forces can be very costly, with sales and marketing costs often consuming 30% or more of a drug's revenues (industry average gross margin is 68%; Reuters, 2005).

2.2 Biotechnology Industry

The biotechnology industry in health care has been characterized by the use of molecular targets and human derived products as well as novel drug delivery systems and technologies for

human therapeutics. These products are often large molecule, organic compounds such as proteins that are more challenging to manufacture than purely chemical entities, but may have an advantage over small molecules with more specific activity in the human body. Traditionally, pharmaceutical companies carried out the majority of drug development and commercialization, but in recent years, biotechnology companies have successfully developed a number of significant new therapies, built marketing and sales capabilities, and are generally obtaining higher rates of approval and faster growth rates than pharmaceutical companies (Wolpert, 2004).

The modern biotechnology industry was founded in 1976, when Herb Boyer of the University of California, San Francisco joined forces with financier Robert Swanson to found Genentech. They used recombinant DNA technology for the first time to make the human protein somatostatin using bacteria (Access Excellence @ National Health Museum, 1999[1]). Genentech went on to successfully produce insulin using recombinant technology, and the applications of genetic engineering and cloning techniques spread rapidly to other research laboratories in the United States in the late 1970s. In 1982, Genentech received the first marketing approval from the FDA for a biotechnology drug product, genetically engineered human insulin. Through the 1980s, the number of biotechnology companies, such as Amgen, Chiron and Cetus Corporation, grew along with numerous advances in biotechnology such as the creation of transgenic animals, recombinant vaccines, and combined antibody-enzyme products. Another important milestone in modern biotechnology was the establishment in 1990 of the Human Genome Project to map all the genes in the human body. In 1993, the Biotechnology Industry Organization was created to form a cohesive voice for this growing industry.

Today, there are over 1400 biotechnology companies in the U.S. alone, with a combined market capitalization of over $300 billion and 2003 revenues of $39 billion (BIO, 2005)[2]. There are over 180 approved biotechnology drugs in a wide range of therapeutic areas and diseases, with 25 new approvals in 2003 alone (BIO, 2005). Appendix 1 lists the top 10 biotechnology companies worldwide by market capitalization. Appendix 2 summarizes some of the key features of the top ten biotechnology companies, including their location, size, corporate positioning statements, and commercial product and development pipeline status. The biotechnology industry is becoming increasingly important in the drug development business, and is enjoying higher drug approval success rates compared to the pharmaceutical industry (Tufts CSDD, 2005). The 5-year average market capitalization growth between 1999 and 2004 for the top 10 biotechnology

[1] All biotechnology history facts in this paragraph are obtained from this source.
[2] Although health care is considered the largest sector, these figures include all sectors of biotechnology.

companies was 22%, versus an average of –1% for the top 10 pharmaceutical companies (Wolpert, 2004).

An important factor in the growth and establishment of successful biotechnology companies has been their location in biotechnology clusters. Clusters are concentrations of companies within an industry sector in a geographic location that increase productivity and innovation and lead to competitive advantage for its member companies (Porter, 1998). In the U.S., the biotechnology industry is heavily concentrated in nine regions: Boston, San Francisco, San Diego, Raleigh-Durham, Seattle, New York/New Jersey, Philadelphia, Los Angeles, and Washington/Baltimore (Cortright and Mayer, 2002). These regions produce close to two-thirds of biotechnology patents, contain over three-quarters of the biotechnology companies, receive close to 90% of the venture capital funding available, and account for 95% of the dollars in research alliances. These clusters and their companies have excelled because of their strong research capabilities and the ability to commercialize that research (Cortright and Mayer, 2002). All of the top ten biotechnology companies have headquarters or a regional office in one of these top clusters (Appendix 2).

Vancouver has an emerging biotechnology cluster that ranks 16th in North America and third in Canada behind Montreal and Toronto (Finlayson and Peacock, 2002), but is the Canadian leader in growth of revenues and research and development spending (Industry Canada, 2004). The increasing strength of the Vancouver biotechnology cluster is supported by a high level of activity in biomedical research and patenting, in particular from the University of British Columbia, and a growing number of successful biotechnology companies (Finlayson and Peacock, 2002), anchored by QLT and Angiotech Pharmaceuticals, and emerging clinical phase companies such as AnorMED Inc. and Cardiome Pharmaceuticals.

2.3 PESTEL Analysis

The following PESTEL analysis (Table 1) highlights the major factors and trends in the macro-environment that are currently influencing the biotechnology industry and could influence the industry in the future. These factors provide opportunities for companies in the industry as well as threats that companies need to beware of. In the following sections, each of these factors will be described in greater detail.

Table 1 PESTEL Analysis of Biotechnology Industry

	Major Factors	Future Trends
Political	▪ Budget deficit in the U.S. leads to increasing pricing pressure from government reimbursement programs. ▪ Government support is available through tax credits for R&D expenses.	▪ Fewer products reimbursed with increased demand for high pharmacoeconomic benefit. ▪ Global competition in industry: continued support for R&D costs to increase national innovation profile.
Economic	▪ Capital markets are relatively unsupportive, driving consolidations, mergers and acquisitions (M&A). ▪ Increasing pricing pressure and backlash against high prescription drug costs. ▪ Markets in the U.S., Europe and Japan are the focus of drug development and commercialization efforts.	▪ Further industry consolidation: small number of dominant, fully integrated companies, increased prevalence of outsourcing and niche companies. ▪ Greater reliance on PBMs to manage high drug costs; reduced pricing flexibility and profit margins. ▪ Developing countries are poised to become the world's largest markets.
Socio-Cultural	▪ Growing aging population drives the demand for health care. ▪ Increased healthcare information is available through the Internet and direct-to-consumer advertising trends, leading to patient empowerment. ▪ Ethical controversies and increased public concern over safety generates negative publicity and unease.	▪ Further strain on public health care systems and costs. ▪ Expanded use of e-health to increased patient empowerment. ▪ Long lead time to increase public support and knowledge of the industry.
Technological	▪ Risk of failure to show safety and efficacy is high, and drug approvals are declining. ▪ Trend toward better diagnostics, genomics and personalized medicine (right drug, indication and dose).	▪ High competition and price for licensing best technology from discovery and research organizations. ▪ Change in the drug development business model from treatment to cure based.
Environmental	▪ Drug manufacturing strictly regulated for quality control.	▪ Increased vigilance of manufacturing processes, which increases costs.
Legal	▪ Intellectual property laws protect newly patented products and create barriers to entry. ▪ Regulatory oversight of industry requires specific drug development processes.	▪ Shift towards narrow vs. broad patent claims reduces the value while requiring higher patenting activity. ▪ Tighter regulatory controls due to product withdrawals (e.g. Vioxx®) increases risks and costs.

2.3.1 Political

Key factors that influence the sales and success of marketed drug products include the reimbursement situation from government programs such as Medicare and Medicaid in Canada and the U.S., and their European equivalents. Good safety and efficacy data from pivotal clinical trials provide support for reimbursement, as well as pharmacoeconomic studies showing net benefits to the health care system. Pharmacoeconomic evidence is becoming increasingly important, and companies that can provide strong pharmacoeconomic data will have an advantage in gaining attractive reimbursement coverage for their products, critical for getting higher market acceptance of the product. As the U.S. budget deficit and aging population grows, however, there will be increasing pricing pressure on products that are reimbursed by government programs. Health care providers are also being pressured to switch to lower cost, generic products wherever possible (Tufts CSDD, 2005). This pricing pressure and reimbursement situation leads to two major options for drug development companies: show high pharmacoeconomic benefit, or focus on patient-payer markets, where reimbursement issues do not apply.

In order to promote research and development programs, Canada and the U.S. currently offer tax credits for research and development expenses. Within Canada, this program is known as the Scientific Research and Development Program (SR&ED), and has grown to become a lucrative incentive for Canadian technology companies to conduct research and development in Canada. At the provincial level, British Columbia also offers SR&ED tax credits, and when combined with the federal program, a company can receive a total of 30% in tax credits for qualifying research and development expenses incurred. In the U.S., a 20% tax credit can be applied to incremental research and development expenses (Ontario Investment Service, 2005). The Canadian government is currently building a long-term strategy for the SR&ED program to improve the business capacity for innovation nationally (The Conference Board of Canada, 2001). Biotechnology companies should extract the greatest value from research and development tax credits and take advantage of these incentives. For companies that carry out research and development in both the U.S. and Canada, an effective business and tax strategy must be devised to maximize the tax credits received through these programs and match the highest research and development costs with the most favourable tax credit program.

2.3.2 Economic

The drug development business relative to other industries is highly profitable, with an average profit of 25% of sales for pharmaceutical companies (Bailey, 2005). However, the industry is very capital intensive, and requires highly specialized knowledge. The high cost and challenges of clinical testing and manufacturing process development and validation provide strong barriers to entry, making the business attractive for established industry players and also for investors, despite the costs and high risk.

The biotechnology industry needs to be aware of the economic forces and trends affecting the industry and threatening its profitability. These forces include the availability of investment capital, pricing pressure from government agencies and consumers, and increased competition within the industry. In the late 1990s, the biotechnology sector was very popular with investors, as it was perceived as a high growth industry with huge potential to transform the field of medical treatment. The biotechnology index in 2000 had huge multiples of market capitalization relative to earnings at that time, based on the perceived promise. Along with the majority of the sector, QLT's market capitalization grew to a peak of US$80 per share in August 2000. However, biotechnology stocks fell out of favour along with the high technology stocks by the end of 2000, and companies were once again being evaluated on fundamentals such as profitability and earnings per share, rather than simply on future growth potential.

As prominent commercial drugs fail and fewer pipeline products reach the market despite higher R&D costs, the industry may be perceived as more and more risky, and investors may become less willing to provide capital to early stage biotechnology companies. These biotechnology companies will be forced to partner with more senior biotechnology companies with free cash flow, or with large pharmaceutical companies in a drive towards merger and acquisition. Some companies will be driven towards consolidation as a way to achieve critical mass and ultimately reduce the risk of failure (Robinson, 2003). Over the next few years, outsourcing clinical trials, discovery, development and manufacturing will become more common as companies look to offset rising R&D costs (Burrill, 2005). Therefore, for a company to maintain independence, it is essential that target markets are carefully selected and focused on areas with large pharmacoeconomic benefits, which in turn generate free cash flow to fund further pipeline development.

The industry also needs to be aware of the increasing resistance to the high cost of prescription drugs, which threatens the profitability of the industry. In addition to the government

pricing pressure discussed in section 2.3.1, insurance companies that cover a high proportion of health care costs in the U.S. are also exerting pricing pressure on drug companies through setting guidelines for reimbursement of patient health care costs, which include restrictions on the drugs that will be reimbursed (Tufts CSDD, 2005). Due to the combined forces of the government and insurance companies, physicians are under growing pressure to choose cheaper alternatives for treating patients (Tufts CSDD, 2005). Trends such as co-payment for drugs by patients are also increasing consumer awareness of high drug costs and increasing the backlash against high prices, despite industry efforts to show an economic benefit to the overall health care system (e.g. Gladwell, 2004). Many large employers are turning to Pharmacy Benefit Managers (PBMs) to help with managing rising drugs costs and using them to negotiate better prices with pharmaceutical companies (Gladwell, 2004), and biotechnology companies should be aware of this trend and ensure that their products get placed on PBM's formularies. As the number of economically empowered patients increases (Burrill, 2005), biotechnology companies should also consider patient-payer markets as discussed in section 2.3.1.

Within the next 25 years, economies in developing countries are poised to become the world's largest markets (Burrill, 2005). Specifically, the markets in Brazil, Russia, India and China are all expected to grow enormously, and the dynamics of the drug development industry in the world market will shift with this growth. Sales for marketed drug products are currently focused on the U.S., Europe and Japan due to their large market size, and these markets will be greatly affected by the growth of developing economies. To remain competitive, biotechnology companies will need to redirect their focus towards these developing countries, and learn how to market their products effectively in these growing new geographical markets.

2.3.3 Socio-cultural

The population demographics are favourable for developing treatments for age-related illnesses, and create a growing demand for health care in general. In the U.S. alone, the population aged 65 years and over is expected to increase from 12.4% in 2000 to 19.6% in 2030, which translates to approximately 35 million people in 2000 to 71 million people in 2030 (Goulding, 2003). Worldwide, the aging population is expected to increase from 6.9% to 12.0% between 2000 and 2030, which translates to an increase of 550 million for a total of 973 million. With this increase in the aging population, there is an added burden on public health care systems and an increase in health care costs to support this growth. This trend reinforces the need for the

biotechnology industry to focus on developing drugs with strong pharmacoeconomic benefits, or drugs that demonstrate cost benefits to the health care industry.

The Internet and direct-to-consumer advertising is also affecting the way information is disseminated in the health care sector. Consumers can readily access health care information on the Internet, research approved treatments and make more informed decisions among the commercial drug products. Drug companies have also increased their spending on direct-to-consumer advertising in an attempt to drive up sales and recover more drug development costs. There is a direct correlation between direct-to-consumer advertising and revenues, as the best-selling drugs have the heaviest consumer marketing programs (GAO, 2002). Better patient knowledge in turn leads to a greater demand for pharmaceuticals in general, and facilitates the market penetration and adoption of new products. There is a trend towards expanded use of e-health (Internet technology in the health care industry), more interactive tools and growth of online Internet communities (Ball, 2001). With increased patient empowerment, however, is the issue of information quality, as misinformation can lead to incorrect, misled or incomplete health care decisions that can jeopardize the patient's health (Shmerling, 2002). Biotechnology companies must therefore carefully manage their communication methods to optimize patient empowerment while minimizing the risks from distributing drug product information directly to patients.

The biotechnology industry has been the focus of controversial ethical debates on genetic engineering, genetically modified food, human cloning and stem cell research (Crabtree, 2001). There is growing public unease with advanced technologies such as genetic engineering that can manipulate life with potentially unknown long-term effects. The mainstream media coverage is primarily centred on these conflicts, rather than the medical research itself, which in turn leads to increased negative publicity across the industry (Abate, 2004). Most large companies have ethics advisory boards to deal with these issues and ensure stakeholder concerns around the ethics of the research and/or technology are taken into consideration. As the younger generation grows up with this technology, the public will become more comfortable and accepting of biotechnology. However, biotechnology companies must be aware of the public perception of industry as a whole and understand the ethical issues surrounding the technology in order to facilitate market adoption of new products.

2.3.4 Technological

The drug development business as a whole has been suffering in recent years from declining research productivity and increased competition within the industry (Tufts CSDD, 2005). The number of New Molecular Entities (NMEs) approved by the regulatory agencies have been declining for pharmaceutical companies since the late 1990s. Compared to small molecule drugs developed by pharmaceutical companies, biotechnology products have been winning higher approval rates from the FDA (Tufts CSDD, 2005). Due to financial constraints, biotechnology companies have not had the luxury of being able to carry out large numbers of projects and build large compound libraries for testing; therefore they have had to take a much more focused approach to drug development using rational drug design and novel approaches to drug delivery and development. The focused approach has been providing biotechnology companies with a competitive edge, leading to higher clinical success rates than large pharmaceutical companies.

There is also an increasing trend towards a biology-centric discovery process based on systems biology that will change the overall drug development process through the use of modelling and simulation technologies, leading to accelerated discovery and lower attrition rates (Burrill, 2005). Companies that want to maintain their competitive edge should continue focusing on novel drug design and delivery methods, as well as novel markets with a high degree of unmet medical need. Drug delivery systems that use proprietary devices are desirable for physicians because doctors have more control over patient treatment, leading to increased compliance and efficacy, and higher reimbursement rates for the physician because they are paid for carrying out a procedure, not just the patient visit.

Some new trends in the biotechnology industry that threaten established companies include advances in genomics, diagnostics, and the pending advent of personalized medicine. These directions can also be perceived as opportunities for strategic and innovative biotechnology companies. Advances in understanding of the human genome may lead to better diagnostics and differentiation of genotypes for gene-based diseases. This differentiation will in turn lead to personalized medicine, in which different therapeutics will be optimal for different genotypes. Personalized medicine is a step towards eliminating adverse drug reactions, the leading cause of hospitalizations, by developing the right drug, for the right indication, at the right dose for a particular patient (Burrill, 2005). Genetic engineering and personalized medicine may also lead to the ultimate goal of medicine, which is to provide cures for medical conditions rather than the symptomatic treatment of diseases that are prevalent today. Biotechnology companies need to

address the growing importance of genomics, genetic engineering, and personalized medicine and consider ways to incorporate these trends into their business models and strategies.

2.3.5 Environmental

Drug manufacturing is regulated for quality control under the FDA regulations known as Good Manufacturing Practice (GMP; US Food and Drug Administration, 2004). Components of this regulation address manufacturing quality control in terms of organization and personnel, buildings and facilities, equipment, components of drug product containers and closures, production and process controls, packaging and labelling controls, and holding and distribution, laboratory controls, records and reports, and returned and salvaged drug products (Mathieu, 2002). Quality can be achieved by minimizing the risk of contamination and errors during manufacturing, and by controlling each step of the manufacturing process. The FDA regulates and inspects all manufacturing sites regardless of geographic location, and therefore biotechnology companies that rely on manufacturing sites outside of the U.S. need to ensure the overseas facilities are GMP compliant.

The FDA is moving away from product-based inspections and towards a system-based GMP inspectional approach that focuses on six manufacturer systems: quality, production, laboratory controls, facilities and equipment, material and packaging and labelling (Mathieu, 2002). This has lead to more efficient GMP inspections and a more risk based approach towards regulating manufacturing processes. Prominent GMP issues include testing and approval, laboratory controls and equipment cleaning and maintenance (Stevens and Stevenson, 2003). Warning letters are issued for any non-compliance, and deadlines are given to rectify any issues raised during the inspection. Failure to comply can result in legal action. Biotechnology companies need to be aware of these environmental factors and understand the impact of GMP non-compliance on product development and approval. Chiron was recently charged with manufacturing violations of their flu vaccine Fluvirin® during the 2004 flu season in the U.S., which created a massive shortage as 46-48 million doses (half of the total flu vaccine supplied to the U.S.) were undeliverable (Hogan & Hartson LLP, 2005). This incident sends a strong message to biotechnology companies that the FDA is becoming increasingly vigilant in the regulation of manufacturing practices.

2.3.6 Legal

Intellectual property is an important aspect of the drug development process, because patents protect new innovations and provide 20 years of exclusive rights to the patent-holder to manufacture and market a product, leading to significant barriers to entry. Intellectual property is also an important criterion for selecting appropriate research programs. Before a research program proceeds, companies need to asses the intellectual property position to determine the available scope of protection and whether the innovation can be adequately protected from competitors during development and initial market introduction.

Once a patent expires, generic competition usually enters and subsequently erodes market share. Depending on the development timelines, which can take 10 to 15 years, the window of opportunity to maximize revenues after product launch can be very short. Biotechnology companies should file patent applications as late in the development process as possible, prior to publishing material on new innovations and submitting the IND. Companies also need to maximize revenues by building sales as quickly as possible after commercial launch to maximize the time the branded product has on the market before generic entry.

Recent trends in patent protection for drug products have forced drug development companies to make narrow rather than broad claims for new technologies. Therefore a biotechnology company developing platform technologies to target several disease areas must file separate patents for each specific therapeutic indication.

Intellectual property protection is an issue in developing countries, particularly in Asia (Borrell, 2005). Biotechnology and pharmaceutical companies with foreign operations in these countries currently have no legal protection against patent infringements on their products or processes. The Chinese government recently declared Pfizer's patent on Viagra® invalid in China, a decision that could deter other pharmaceutical companies from expanding operations into Asia (Yu, 2004). For the first time, generic companies fought Pfizer's patent in the courts rather than ignoring the legal protection altogether, which is a small step in the right direction. Based on the resolution of this case, however, China is still years away from providing adequate patent protection. As world markets in developing countries become increasingly important, biotechnologies companies must be aware of the legal implications of doing business in these less developed countries.

The majority of litigation cases from patent infringements are filed in the U.S., and the process is costly and time-consuming (Alexander, 2004). According to Alexander, average costs for litigations in the U.S. range from $2 to $2.5 million, and the results can be contested, leading to several appeals and jury trials. In turn, the costs to the organization can be higher in terms of adverse publicity and resource requirements. Biotechnology companies therefore need to be clear on their intellectual property position and ensure adequate scope of protection with their patents in order to remain competitive and avoid costly legal battles.

Despite the high patenting activity in the industry, which protects companies from generic competitors, there is evidence that first-to market advantages have been declining (DiMasi and Paquette, 2004), making intellectual property protection secondary to improved efficacy and safety outcomes for successful marketing of new products. Within the industry, competition for attractive markets has been increasing, with the average period of market exclusivity declining from 10 years in the 1970s to less than 2 years by the late 1990s (DiMasi and Paquette, 2004). These results indicate that barriers to entry to new markets have been falling, and that drug companies are in a heated race to gain approval to these new markets with different products that do not infringe on patents. Biotechnology companies need to respond by developing better products with innovative modes of action that are hard to replicate, rather than relying on patents to preserve competitive advantage in a market.

2.3.7 PESTEL Summary

The PESTEL analysis shows that the industry is threatened by rising costs and increased risk from multiple sources, which will force greater consolidation among companies in an attempt to reduce these costs and risks. Biotechnology companies that remain aware of the major factors and future trends that influence the industry will retain a competitive edge over others and have a higher chance of sustainability. While there is a general trend towards increasing pricing pressure from government reimbursement programs due to rising health care costs and the aging population, biotechnology companies have the opportunity to develop therapeutics for the aging population as health care demand increases. There is also the opportunity to expand into patient-payer markets where reimbursement is not an issue as more patients become economically empowered and increase their knowledge through e-health and direct-to-consumer advertising.

With rising R&D costs, biotechnology companies have the opportunity to outsource segments of the drug development value chain and build competencies in developing countries,

which facilitates eventual expansion into these future world markets. As the regulatory environment becomes increasingly conservative due to recent product recalls and manufacturing violations, biotechnology companies can move towards more advanced and innovative technologies using systems biology to accelerate development timelines and reduce the regulatory risk and attrition rates. Developing personalized medicine can also reduce regulatory risks, but will require developing new models within the industry for gaining regulatory approval and generating profits, because the premise of high profit margins from economies of scale and significant market share will be challenged. Companies that are able to devise development and marketing strategies early on to support profitability in the coming era of personalized medicine will be best positioned to survive and thrive.

2.4 Business Models

Business models in the biotechnology industry have evolved over time, starting with the fully integrated biopharmaceutical company (FIPCO) business model adopted by Genentech, the first biotechnology company formed in 1976 (Fisken and Rutherford, 2002). When the biotechnology industry started in the mid-1970s, the main business model was focused on scientific discovery and development, and companies developed core competencies in the discovery of biologically derived therapeutic drugs (Wolpert, 2004). Biotechnology companies operated on the assumption that they did not need to obtain competencies in regulatory affairs, marketing and distribution of drugs to patients and the medical community, as these competencies were only relevant to pharmaceutical business model. The scientific approach to drug development was also different than the pharmaceutical approach, and biotechnology companies used biology as a basis to identify drug targets and used biological materials to design drugs.

As the biotechnology industry matured in the 1980s and 1990s and launched successful products, they gained greater access to capital markets and more financial flexibility (Wolpert, 2004). The leaders in the biotechnology industry moved towards a more integrated business model, blending science, clinical development and commercialization together in order to retain more of the drug profits for themselves. During this time, the pharmaceutical business model was also adapted to include more biotechnology science capabilities, although this model continues to rely predominately on the chemical synthesis of small molecules for drug development.

Table 2 shows the major components of a fully integrated biopharmaceutical value chain.

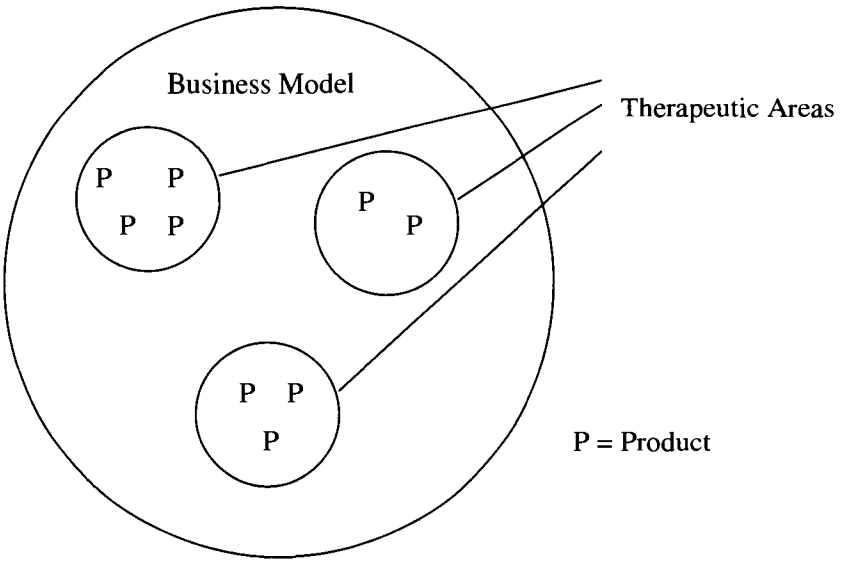
Table 2 Fully Integrated Biopharmaceutical Value Chain

Category	Stage	Activity	Core Competency
Research	Target Discovery	Targets are identified for therapeutic development.	Scientific expertise, intellectual property, and research and development operations
Research / Development	Lead Discovery & Development	Potential therapeutics are identified to remedy the target. Preclinical trials in animal models.	Scientific expertise, intellectual property, and research and development
Development	Clinical Trials & Regulatory Approval	Leads are tested in human models for efficacy and safety. The ideal end result is FDA approval.	Clinical expertise, trial design, and FDA interaction
Development/ Commercialization	Manufacturing	Manufacturing process of the drug is developed and implemented.	Process science and engineering, and FDA interaction.
Commercialization	Marketing, Sales, Distribution	Targeting, educating, and distributing the product to the appropriate consumer.	Marketing capabilities, Distribution channels, sales force and support, and relationships with doctors and payers.

Over the years since the founding of Genentech, the FIPCO business model has adapted to changing market and economic conditions, and three additional biotechnology business models have emerged, described in more detail below. Specialty pharmaceutical companies have also formed their own business models, and most companies use a combination of the four main business models found in the industry (Patel, 2004).

Success in the biotechnology business model generally means focusing on specific therapeutic areas for building its core capabilities (Wolpert, 2004). Figure 2 depicts how the business model, therapeutic areas, and products are related in the biotechnology industry.

Figure 2 Depiction of Biotechnology Business Model Hierarchy



The business model is the overarching level, and encompasses the way in which a company creates and sustains value. The therapeutic areas are the specific medical fields on which a company focuses to build their core capabilities and differentiate from competitors. In the platform model described below, technologies or platforms may replace the therapeutic areas depicted in Figure 2. The company's business model and therapeutic areas are within the domain of the corporate strategy. Individual products fall within therapeutic areas, and are the domain of business unit strategy, which will be discussed to a lesser extent in this report.

2.4.1 Biotechnology Business Models

The FIPCO business model is vertically integrated along the value chain, and combines research, development, manufacturing and marketing capabilities within one company. A company can generate value across the entire drug development value chain by managing and controlling all aspects from development through to commercialization (Fisken and Rutherford, 2002). According to Fisken & Rutherford, because of the high financing requirements to set-up and maintain the broad infrastructure, this business model is only feasible for highly profitable companies that have access to a wide range of skills and capabilities. Significantly for QLT's strategic vision, all of the biotechnology market leaders listed in Appendix 1 use the FIPCO business model to generate high returns and sustain growth, retaining their own marketing and sales force.

Other business models that have emerged include the product model, the platform/tool model, and the hybrid model that combines the product and platform/tool models. In the product model, a company undertakes drug discovery and development and out-licenses their product to pharmaceutical or top biotechnology companies for commercialization (Fisken and Rutherford, 2002). More mature companies with substantial cash flow undertake commercialization efforts themselves in an effort to move up the value chain towards the FIPCO model. Partnerships, strategic alliances and outsourcing are essential to the product model to sustain competitive advantage.

The platform/tool model encompasses discovery and development of platform technologies or new research tools, informatics, services and/or reagents to aid drug development, and value is generated through licensing, subscriptions and service fees (Fisken and Rutherford, 2002). According to Fisken & Rutherford, few companies follow this model due to commoditization and threat of technology obsolescence, and most biotechnology companies use the hybrid model where platform technologies are used to develop a pipeline of products, and the technology is either developed internally or in-licensed. For the hybrid model, commercialization is out-licensed to pharmaceutical or top biotechnology companies through partnerships, strategic alliances or outsourcing agreements.

2.4.2 Specialty Pharmaceutical Business Models

Specialty pharmaceutical companies are involved in the discovery, development and/or marketing of new and existing specialty drugs (Patel, 2004). These companies are distinguished from biotechnology companies in their lack of focus on biologic targets, biologic products, or novel delivery methods with novel products. There are four main business models used in this industry, and most companies use a mix of these models. In the "buy and promote" model, a company acquires currently marketed products from pharmaceutical companies that are promising yet have low sales. Through targeted marketing efforts, revenues for these products are increased (Neville, 2004). In the drug delivery model, new drug delivery technologies are used to reformulate existing products to increase convenience and efficacy, or to develop new indications for existing products (Patel, 2004). These new products are then either out-licensed to pharmaceutical companies for late stage clinical development and commercialization, or developed internally. Internally developed products are then either commercialized internally or out-licensed to pharmaceutical companies for sales and marketing.

Another model is to in-license promising products for late stage development and commercialization (Patel, 2004). Companies can partner with small to medium sized firms to take a product to market, thereby reducing the risk of taking a drug to market alone. Drug delivery platforms are also in-licensed by speciality pharmaceutical companies to facilitate rapid, cost-effective development (Doyon, R., 2004). The fourth business model is the new drug discovery model where companies undertake research to discover new drugs, and then out-license their product to pharmaceutical companies for development and commercialization (Patel, 2004). An emerging business model for specialty pharmaceutical companies is the "no research, development only" (NRDO) model (Thiel, 2004). In this model, companies carry out no drug discovery or research and focus entirely on developing clinical-stage products that are in-licensed. This business model avoids the riskiest phases of drug development, and uses revenues generated from marketing in-licensed products to acquire further in-licensed products. Companies need to consider the strategic fit and potential of a product in determining whether to in-license, out-license or commercialize it themselves.

2.5 Business Valuations: Market Leaders and Comparables

The financial information for large market capitalization biotechnology companies as well as speciality pharmaceutical companies is analyzed here to provide a basis for comparison with QLT in subsequent chapters.

2.5.1 Large Market Capitalization Biotechnology Companies

Relative to other industries, successful biotechnology companies enjoy a large market capitalization due to their high growth rate and high profit margins. Key financial information for the ten largest market capitalization biotechnology companies is summarized in Appendix 1. The market capitalization ranges from $3.43 billion to $77.24 billion, with a large fluctuation within this range. Higher valuations seem to be most closely associated with a combination of high revenues from strong commercial products, and high earnings growth rates, which are in turn related to the depth and market potential of the development product pipeline. All of these top ten biotechnology companies have a large number of commercial products, a large pipeline, or both (Appendix 2). The large number of commercial and pipeline products allows these companies to diversify their revenues and mitigate the risk of market or product development failures, which is rewarded by financial analysts and investors by higher valuations.

Amgen, with the highest market capitalization of $77.24 billion, is the most successful biotechnology company and has 1.5 times the market capitalization of the second ranked company, Genentech (market capitalization $49.76 billion). Amgen is also well ahead of the other companies in terms of revenue ($10.55 billion, twice that of Genentech), and earnings ($2.36 billion, three times the earnings of Genentech). Overall, revenues are in the range of $389 million to $10.55 billion, and most companies are earning profits within the last 12 months. High revenues are associated with successful commercial products with large sales, and control over these revenue streams from self-marketing these products.

Growth among the large market capitalization biotechnology companies varies considerably. The earnings growth rate ranges from 15% to 70% with Chiron in the lead and MedImmune close behind. Average annual sales growth for the top ten biotechnology companies was 39% between 1999 and 2004 (Wolpert, 2004). The average net profit margin for this top ten group was 17%, with a range of -2% to 49%. As a comparison, QLT's net margin was 3%. The highest revenue companies had high valuations regardless of their net margins, whereas the 8th and 9th ranked companies, Chiron and MedImmune, may have high valuations in part because of their extraordinarily high net margins of 29% and 49% respectively.

For profitable companies, earnings ratios provide a valid basis for comparison. The price to earnings ratio (P/E) ranges from approximately 19 to 279. Companies with high market capitalization and low earnings will have abnormally high P/E ratios, as with MedImmune, Inc. Excluding this value (279), the P/E ranges from approximately 19 to 106, with Chiron leading by 1.6 times the second highest P/E (Genentech at 65). The price to earnings to growth ratio (PEG) ranges from 1.14 to 2.13, excluding MedImmune, Inc due to the abnormally high PEG ratio based on an abnormally high P/E ratio.

2.5.2 Specialty Pharmaceutical Companies

The market capitalization of specialty pharmaceutical companies is generally lower than the large market capitalization biotechnology companies listed in Appendix 1 because of the perception of lower potential returns due to less innovative products and platforms. However these companies were chosen as comparables based on their pipeline. Financial information for comparable specialty pharmaceutical companies is listed in Appendix 3[3]. The market capitalization ranges from $218 million to $15 billion with Forest Laboratories, Inc in the lead at

[3] Specialty Pharmaceutical comparables were identified in the "Opinion of Financial Advisor – QLT" section of the Joint Proxy/Prospectus Form S-4 (QLT Inc., 2004, October).

1.5 times the market capitalization of the second ranked company, Allergan ($10 billion). Revenues also vary widely from $100 million to $3 billion, and Forest Laboratories has the highest sales. Positive earnings range from $19 million to $897 million, with a few companies recording losses in the trailing 12 months.

In terms of valuation multiples, the P/E varies by a factor of 10 from approximately 11 to 134 (excluding King Pharmaceuticals due to low earnings and high market capitalization) with Biovail Corp. in the lead. PEG varies widely from 0.71 to 1.49, again excluding King Pharmaceuticals for reasons stated previously.

In terms of growth, there is less comparison due to negative earnings for some companies. While King Pharmaceuticals and Biovail Corp. have extremely high earnings growth rates due to high market capitalization and low earnings, the norm varies from 16% (Shire Pharmaceuticals) to 67% (Connetics Corporation).

2.6 Business Strategies: Market Leaders

Market capitalization in the biotechnology industry is driven by sales estimates for its pipeline and sales performance of its commercial products (Wolpert, 2004). Therefore, to increase market capitalization, a company must launch successful products as well as maintain a healthy R&D pipeline with realizable market value. An analysis of the top ten biotechnology and pharmaceutical companies from 1999 to 2004 shows that higher multiples were generated due to "adequate or better scientific success," while low multiples were evident in companies that experienced "heightened scientific risks and explicit strategic management issues" (Wolpert, 2004). Examples of strategic management issues that lead to poor market performance are FDA manufacturing violations, SEC infringements and litigation cases involving product use. Effective strategic management is driven by the ability to focus on core capabilities, drive top line growth, drive efficiencies, contain risk and exploit deal opportunities.

Business development deal opportunities provide a means for executing corporate strategies, and therefore good strategic management and scientific success are essential for generating a high valuation that can lead to better negotiating power and deal terms for a company. Typical deal types for the drug development industry include the following (Wolpert, 2004):

- Merger of equals
- Large enterprise acquisitions

- Bolt-on acquisitions
- Product-level alliances
- Restructurings, including divestures, spin-offs, equity carve-outs

Wolpert (2004) predicts that within the biotechnology industry, bolt-on acquisitions are likely to take precedence over merger and acquisitions due to the high capital market performance and independent growth within the top ten biotechnology companies. However, he warns against the trend towards merger and acquisitions, because his research indicates that there is no inherent strategic or growth advantage in these types of deals. In addition, he expects growth to be based on the need to drive innovation: "Repeatedly, the corporate development question is not "do we grow through acquisition or organically?" but "are there assets to be acquired that are of a higher quality than those we might develop or sell organically?" These are important questions that biotechnology companies need to address as they position themselves for growth.

2.7 Conclusions from Industry Analysis

The biotechnology industry has become a major contributor to the drug development business, and is outperforming the pharmaceutical industry in terms of regulatory approval rates and growth based on market capitalization. There are, however, many factors influencing the industry, and the external environment is likely to become more complex as the industry matures. High R&D costs and long development timelines are common, along with a low probability of product success. More consolidations are likely to occur to offset the high cost and risk, as well as outsourcing and shift in focus towards developing countries. As the regulatory environment becomes increasingly conservative and demanding, and reimbursement issues become more dominant, the industry is likely to move towards patient-payer markets and innovative technologies to offset these risks. Personalized medicine is another approach the industry will take to reduce regulatory risk, yet this challenges the dominant business models based on economies of scale and market dominance.

Analysis of the top ten biotechnology companies indicates that the FIPCO business model is the most successful at generating and sustaining growth, although strong scientific success is also necessary to achieve high multiples. Throughout the industry, mergers and acquisitions have been used to execute corporate strategies, yet analysts advise against these growth strategies as they fail to provide any strategic or growth advantages. Ultimately, biotechnology companies must not compromise quality for the sake of growth. We analyze QLT's

internal assets and environment in the following chapter, and identify the gaps in QLT's current capabilities to help determine the best strategy for the company to optimize its growth potential.

3 QLT INTERNAL ENVIRONMENT

The purpose of this chapter is to analyze QLT's internal environment in order to provide a foundation for our proposed growth strategies. We outline QLT's current financial situation and valuation, and evaluate its business model and business focus. We use a growth matrix to determine the growth opportunities and high-level gaps in the pipeline relative to QLT's growth target. We also evaluate the current revenue streams, the current pipeline of the company, and estimate the potential value of QLT's products and cash flow over the next several years to determine the specific levels of income shortfall relative to the growth target. In addition, we provide an analysis of QLT's core capabilities, a SWOT analysis of the company's strengths, weaknesses, threats, and opportunities, and a stakeholder analysis to provide a solid basis for our growth strategy recommendations in the following chapter.

3.1 Financial Situation and Valuation

QLT has been profitable since 2000, when Visudyne® was approved and began generating revenues for the company (QLT Inc., 2004, March 12). Detailed income statement and balance sheet data from 2000 to 2004 are provided in Appendix 4. QLT's revenue growth since 2000 has been impressive, increasing from $32 million to $186 million in 2004, representing an average annual growth rate of 81% over the period. Net income levels have fluctuated to a greater extent, but have also grown from $4.4 million in 2000 to $57 million in 2004, over a ten-fold increase over the 5-year period. The year over year growth from 2003 to 2004 was 27% for revenues and net income. This level of growth may be more representative for the company as the market for Visudyne® matures, versus the rapid growth rates in the first 2 years after commercial launch. Net profit margins average 36% over the period 2000 to 2004. QLT had a cash balance of approximately $380 million at the end of 2004 (QLT Inc., 2005, February 23), which represents the amount of capital easily accessible for any business development deals in the near term. The outlook for 2005 provided by QLT in February 2005 is for continued strong growth in revenues, in the $255 to $280 million range, for projected year over year growth of 8% to 15%.

QLT's current market capitalization is in the low $1 billion range (Appendix 1), with approximately 92 million common shares outstanding (QLT Inc., 2005, February 23). The

company has a price to earnings ratio of 21 based on 2003 revenues and earnings. Compared to the biotechnology industry leaders, this P/E is low, with only Serono S.A. having a lower multiple at 19. The average P/E ratio for the profitable market leaders is 87. At this P/E ratio, QLT would have a market capitalization of around $4.4 billion, putting it very close to the top 10 biotechnology companies. A further analysis of QLT's financial situation shows that the profit margin, at 31%, is higher relative to the biotechnology leaders, who average 17%, excluding the two unprofitable companies. QLT's P/E to growth (PEG) ratio, at 0.75, is also substantially lower than the market leader average of 1.88, suggesting that QLT has a lower valuation relative to its expected rate of growth than any of the market leaders. None of this financial data sufficiently explains why QLT has such a low market capitalization compared to the market leaders.

The explanation for the low valuation perhaps lies in the perception investors have of QLT's product potential and pipeline. Possible reasons for QLT's low valuation include discounting the growth estimates due to threat of competitors in commercial markets, the potential development risks of upcoming products in the pipeline, and uncertainty about QLT's ability to deliver on their corporate strategy and successfully complete integration following its recent merger. There is also the possibility that QLT's multiple is driven by categorization with the specialty pharmaceutical companies, which generally have lower multiples than biotechnology companies.

The following sections in this chapter will examine the product pipeline in more detail to determine if discounting due to pipeline reasons is a valid concern, and will examine the company's capabilities in more detail to determine if there are any obvious strategic shortcomings. Chapters 4 and 5 will then address the strategies that QLT can use to change investor perceptions and increase its valuation.

3.2 Business Model and Therapeutic Focus

QLT's currently business model can be classified under the hybrid biotechnology model described in section 2.4.1, combining product development with a platform and technology development model. With the acquisition of Atrix, the company also employs a combination of specialty pharmaceutical models, including the drug delivery, in-licensing, and new drug discovery models described in section 2.4.2.

QLT does not yet follow the FIPCO model employed by the successful, large market capitalization biotechnology companies. The company is currently somewhat integrated along the value chain. The company has the following capabilities in house:

- Discovery and Research
- Preclinical Development
- Clinical Development
- Manufacturing, including a cGMP facility and a pilot manufacturing facility under construction.
- Market research and marketing strategy

Despite the manufacturing facilities, QLT is dependent on contract manufacturers for a large portion of Visudyne® manufacturing. The company also has relationships with medical device companies for the development and marketing of its light devices used in conjunction with its drugs for photodynamic therapy (QLT Inc., 2004, October 19). Furthermore, the company does not have a commercial presence, and currently partners with large pharmaceutical companies for sales and marketing of its commercial products. These marketing partners include a strategic alliance with Novartis for Visudyne®, Sanofi-Aventis for Eligard® and Sandoz for generic dermatology products.

The company depends heavily on intellectual property for strategic advantages, and owns or has rights to a number of patents covering its products. QLT files new patent applications as applicable, or relies on trade secrets to maintain competitive advantage (QLT Inc., 2004, October 19).

QLT is actively involved in developing and commercializing products for a number of different therapeutic areas, with a focus on eye diseases, cancer, and dermatological and urological conditions. The company is also looking for opportunities to expand its pipeline through strategic acquisitions, in-licensing, or other forms of collaboration. The company has commercialized two products for cancer, Eligard® and Photofrin®. Visudyne® has been commercialized for a number of eye diseases. A dermatology product for acne, Aczone™, is currently undergoing FDA review for marketing approval. The urological condition, benign prostatic hyperplasia, is being explored with a PDT product, lemuteporfin, currently in clinical

development. Details on these products and other pipeline products are provided in the following sections.

3.3 Growth Strategy

QLT is dependent on continued development of new products for growth. QLT Inc has a few products in its development pipeline and a number of commercial products in its core therapeutic areas. Appendix 5 shows the development stage of each product in its therapeutic indication. In order to analyze the potential gaps in company growth, we have classified each of the products into the following growth matrix (Table 3).

Table 3 Growth Matrix of QLT's Development Products

	Existing Products	**New Products**
Existing Markets	***Market Penetration*** ▪ Visudyne® in AMD (Ophthalmology) ▪ Eligard® in Prostate Cancer (Urology) ▪ Generic Dermatology	***Product Development*** ▪ Aczone™ in Acne (Dermatology) ▪ Lemuteporfin in Acne (Dermatology) ▪ Lemuteporfin in BPH (Urology)
New Markets	***Market development*** ▪ None	***Diversification*** ▪ Aczone™ in Rosacea (Dermatology) ▪ Atrigel®-Octreotide in carcinoid tumour (Cancer) ▪ Bone regeneration (with Pfizer) ▪ Atrigel® peri-ocular delivery (Ophthalmology)

QLT's growth strategy is currently strong in existing markets, as shown above by the number of products in the market penetration and product development areas. However, QLT is not currently pursuing new markets very strongly, with four new products using the diversification strategy, and none in market development. Furthermore, the bone regeneration product is being developed by Pfizer, with clinical supplies and consulting being provided by QLT, and therefore has limited growth potential for QLT. We revisit this matrix and growth strategies for QLT in Chapter 4.

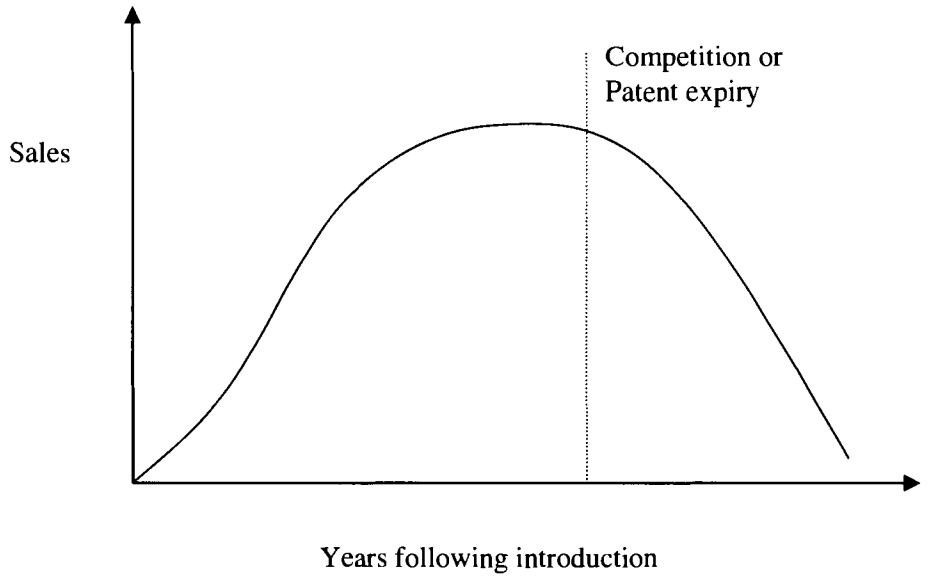
3.4 Products and Pipeline Value

This section evaluates the revenue-generating potential of the commercial products and the pipeline products in order to provide a quantitative basis for analyzing potential shortfalls relative to the QLT's valuation target in 2010. The intention of these financial projections is not to provide a highly accurate or precise forecast of expected sales, but rather to generate an estimate of when there might be gaps in QLT's income growth.

For the commercial products, we provide market size and growth potential, and estimate future revenues based on the competitive landscape and status of intellectual property protection. For the development products, we estimate market potential based on timelines to launch, competitive landscape and intellectual property protection, and provide estimates of future revenues. In section 3.4.3, we summarize the revenue-generating potential of QLT's commercial products and pipeline over the next 10 years, and outline potential shortfalls in the revenue generating potential relative to the growth and valuation target of the company.

We used public information about the market size and growth rates for each indication where available. For QLT's target market share, we applied the standard market adoption and life cycle curve for new medical products shown in Figure 3. Note that this figure does not include the lengthy development times. We estimated relatively rapid growth in the market, reaching peak market share at 3-5 years after launch, and then a gradual decline in the market due to assumed entry of competitors and next generation products. We did not assume that QLT would retain peak market share until patent expiry because with the exception of Visudyne®, none of the markets which QLT is pursuing have wholly unmet medical needs, and there are generally established competitors. The peak market share for QLT to target was based on the degree of current competition in the market, and an assumption that QLT's product would show some competitive advantage over current treatments. Detailed assumptions for each product are shown in the accompanying appendices.

Figure 3 Drug Product Life Cycle Curve Following Market Introduction



Source: Adapted from the Association of the British Pharmaceutical Industry (2005)

3.4.1 Commercial Products

Visudyne® was the main marketed treatment for wet AMD, the leading cause of blindness for people over 50 as of January, 2005. Visudyne® is a PDT product, and the treatment involves a two-step process in which Visudyne® is first administered intravenously and collects in neovascular tissue, then is activated by non-thermal light delivered through a device to destroy abnormal cells or tissue treatment. Launched in 2000, Visudyne® has been approved for predominately classic AMD in 72 countries and occult without classic AMD in 40 countries. By 2003, Visudyne® had penetrated 70% of the US market, and current growth strategies are directed towards markets in the rest of the world (QLT Inc., 2004, April 28). Visudyne® sales for 2004 totalled $448 million worldwide (QLT Inc., 2005, January 20).

QLT manufactures and supplies Visudyne®, and has partnered with Novartis in a 50:50 profit share for marketing and distribution (QLT Inc., 2004, September). QLT is currently in Phase III clinical trials with Visudyne® for the treatment of occult without classic AMD in the US. Visudyne® also has an expanded label for choriodal neovascularization (CNV) due to pathologic myopia in 56 countries and CNV due to ocular histoplasmosis in the U.S. Recently, Visudyne®'s patent was extended to 2012 and QLT has a strong IP position in the U.S. and Europe for Visudyne® with PDT (QLT Inc., 2005, February 17).

Sales and revenues estimates for Visudyne® from 2005 to 2015 are shown in Appendix 6. The wet AMD market, valued at $1 billion (Cohen, 2004), is expected to grow due to the increase in the aging population. However, competitor product Macugen® of Eyetech Pharmaceuticals was launched by marketing partner Pfizer in January 2005, and with a number of other wet AMD treatments in development Visudyne®'s market share is expected to decline (Taylor, 2005).

QLT's second largest commercial product by sales is Eligard®, an extended release leuprolide acetate product for the treatment of advanced prostate cancer. For 2004, Eligard® had $84 million in sales world-wide (QLT Inc., 2005, January 26). The 1, 3 and 4-month formulations were launched in 2002 and 2003, and the 6-month formulation was approved by the FDA in December 2004, with commercial launch expected in Q1 2005 (QLT Inc., 2004, December 15). The 1 and 3-month formulations are approved in the U.S. and 24 European countries, while the 4 and 6-month formulations are only approved in the U.S. (QLT Inc., 2004, December 21). Eligard® lowers testosterone levels, which leads to a reduction of symptoms related to prostate cancer (QLT Inc., 2004, December 15). QLT manufactures the product and has partnerships for marketing with Sanofi-Aventis in the US and Canada, Yamanouchi in Europe and Sosei in Japan (QLT Inc., 2005, February 17). Eligard® has patent protection until 2018 (Atrix Laboratories Inc., 2003) and has strong IP protection in the U.S., Europe and Japan (QLT Inc., 2005, February 17). Sales and revenues estimates from 2005 to 2015 are shown in Appendix 7. According to our estimates, peak sales of $100 million are expected during 2005 to 2007.

QLT also has five generic dermatology drugs on the market in partnership with Sandoz, a retail generics company owned by Novartis (Atrix Laboratories Inc., 2004). Lidocaine 2.5% and prilocaine 2.5% cream, a topical anaesthetic, was launched in September 2003. Mometasone Furoate Ointment USP, 0.1%, a topical corticosteriod, was launched in December 2003. Betamethasone Dipropionate Cream USP, 0.05% (Augmented), another topical corticosteriod, was launched in January 2004. Fluticasone Propionate Cream, 0.05%, a topical anti-inflammatory, anti-pruritic agent was launched in May 2004. Erythromycin 3% and Benzoyl Peroxide 5% Topical Gel, USP, an anti-acne medication, was launched in March 2004. QLT has also received tentative approval for Mometasone Furoate Topical Solution, a topical corticosteroid, pending the patent expiry of Elocon® lotion in 2007, and for Mometasone Furoate Cream pending patent expiry of Elocon® cream in 2007. There are currently 4 ANDA (abbreviated NDAs) under review with the FDA for additional generic dermatology products.

Although there are high barriers to entry in the topical generic business (QLT Inc., 2005, February 17), QLT has been the second or later generic manufacturer to receive approval of these generic dermatology products, leading to minimal sales in 2003 of only $314 thousand (Atrix Laboratories Inc., 2004). However, QLT announced expectations of $30-35 million in revenues from generic dermatology products by 2008 at a recent investor presentation (QLT Inc., 2004, December). Sales and revenue projections from 2005 to 2015 are provided in Appendix 8.

3.4.2 Pipeline Products

The most imminent product in QLT's development pipeline is Aczone™, an acne product for the dermatology market. Aczone™ is a topical product for mild to moderate acne incorporating a proven anti-inflammatory drug, dapsone, in a new delivery technology known as SMP™. The NDA for marketing approval for Aczone™ was filed with the U.S. FDA in August 2004, and QLT expects to launch sometime in the third quarter of 2005. Aczone™ will be marketed by Astellas Pharma Inc. (formerly Fujisawa Healthcare Inc). Patent coverage for this product extends until 2022. Financial projections and assumptions for this product are shown in Appendix 9. We estimate that this product could have peak sales of approximately $200 million, although this will depend on the market penetration and the performance of new competitors that may enter the market. Because Aczone™ is partnered with Astellas, we expect QLT revenues to be reduced accordingly.

This product is also being developed for acne rosacea, which is currently in Phase II. We expect this product to be on the market by 2008-9. Off-label use of this product by dermatologists is probable as soon as safety and efficacy in this indication is demonstrated in clinical trials, probably by the end of 2006. Financial projections for Aczone™ in Rosacea are shown in Appendix 10. We estimate peak sales of $375 million by 2013 for this product, with substantially reduced revenues for QLT due to an assumption of profit-sharing with Fujisawa.

The next product in QLT's pipeline is aimed at providing a treatment for benign prostatic hyperplasia, or BPH, a urology indication. QLT's treatment uses photodynamic therapy with lemuteporfin, a third generation photosensitizer. This product has shown safety and preliminary efficacy in a small Phase I/II trial, and QLT intends to carry out a Phase IIb clinical study in 2005 (QLT Inc., 2005, February 17). Financial projections for lemuteporfin in BPH are shown in Appendix 11. Patent coverage secures this product until at least 2017/2018. This product is also estimated to have peak sales of $200 million. There is probably a very wide range in the potential

sales, however, as the BPH market is very competitive, with a range of alternative treatments already established on the market, from drug therapies to a number of minimally invasive treatments, and surgery. QLT retains all marketing rights to this product, and the company could choose to market the product itself if there is sufficient market potential from later clinical results, which would require building an internal urology sales force.

QLT also partnered with Pfizer for a bone regeneration product using the Atrigel® platform, which is currently in Phase II clinical development. This is a 1 billion Euros market that appears to be growing rapidly, at 10% per year (curasan AG, 2005). Financial projections for this product are shown in Appendix 12. Because of lack of information on the licensing agreement, we assumed a 10% royalty rate on sales.

Another product in Phase I/II is Octreotide using Atrigel® for carcinoid tumours. Atrigel® with Octreotide would be competing against an established player in the market, Sandostatin LAR, which had $690 million in sales in 2003 (QLT Inc., 2005, February 17). QLT's competitive advantage would be a 3 month formulation, compared to Sandostatin's once a month treatment. Financial projections for Atrigel®-Octreotide are shown in Appendix 13. We estimate that if no other competitors emerge and QLT is able to win 35% of the market share from Sandostatin, this could be a nearly $300 million per year product, with all commercialization rights retained. Marketing this product internally would require a gastroenterology or oncology sales force.

We did not estimate future values for products in the preclinical phase because of their high degree of uncertainty and probable long development timeframes, making these products unlikely to contribute significantly to QLT's revenues and income within the next 10 years.

3.4.3 Summary of QLT's Revenue and Income Growth Potential

The income potential from all of QLT's current commercial and pipeline products out to 2015 is summarized in Appendix 14. If all of these products achieve the estimated market share and growth rates, QLT may be able to achieve annualized income growth rate of 21% out to 2010, growing from an estimated $70 million income in 2005 to $155 million in 2010. It is important to note, however, that these sales and income projections do not account for major risks such as early entry of significant new competitors to the market or potential failure of pipeline products to achieve target efficacy profiles. The probability of success of the Phase I/II products that make up much of the pipeline is less than 80%, and when this risk is incorporated, the

annualized growth rate of the company drops to 6% between 2005 and 2010, giving an income of $89 million in 2010. We examine the implications of this income growth potential for the company's valuation in section 3.6.

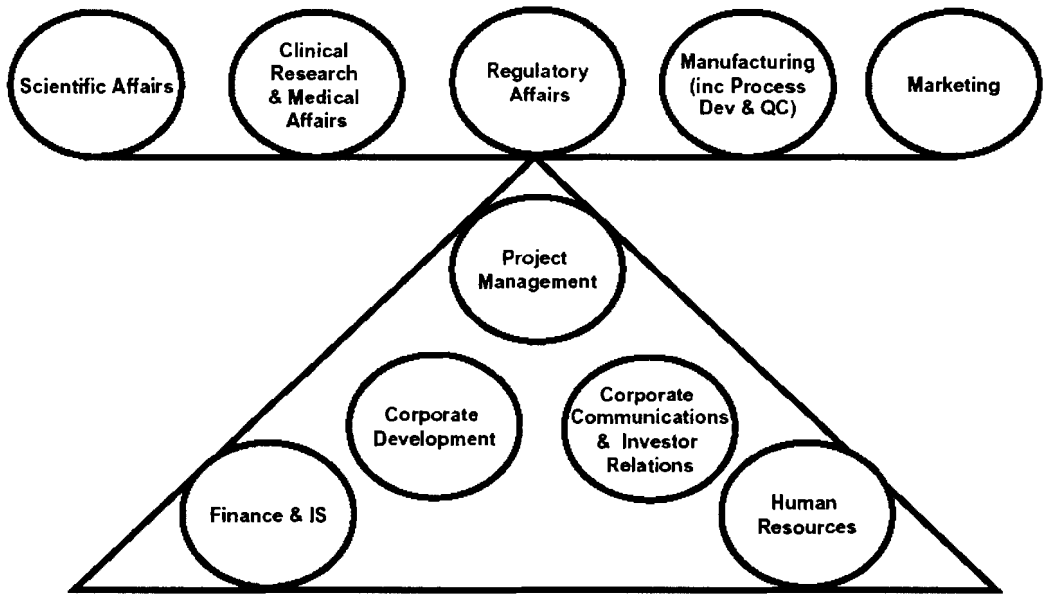
3.5 SWOT Analysis

A firm's capabilities are classified as either threshold capabilities that are required to compete in a given industry, or core capabilities that provide competitive advantage (Leonard, 1995) and are unique to a specific company. A SWOT analysis can be used to determine a firm's competitive position and advantages relative to the industry environment (Woodcock and Bemish, 2003). In this section, we analyze QLT's core capabilities and perform a SWOT analysis to identify the sources of competitive advantage and resource/capabilities gaps in achieving the company's vision of becoming one of the top ten biotechnology company by 2010.

3.5.1 Core Capabilities

Core capabilities can be evaluated by function (Woodcock and Bemish, 2003). QLT has the core drug development and commercialization functions in addition to supporting business functions, shown in Figure 4. The core or essential functions for QLT are: Scientific Affairs, Clinical Research and Medical Affairs, Regulatory Affairs, Manufacturing, and Marketing. The supporting functions QLT are shown in a hierarchical manner, with Project Management being closest or most important to enabling the core functions to operate successfully.

Figure 4 QLT's Core and Supporting Functions



Source: QLT Inc., 2004, September.

We believe that QLT has a number of core capabilities at the corporate level that give the company a competitive advantage relative to the industry and position the firm for future growth:

- Targeted drug delivery platforms - QLT is a world leader in PDT (QLT Inc., 2004, September) and has developed three generations of photosensitizers (Photofrin®, Visudyne® and Lemuteporfrin) (QLT Inc., 2004, April 28). Additional proprietary drug delivery platforms provide flexible platform technologies for new product opportunities (QLT Inc., 2005, February 17).

- Combination products - QLT's expertise in PDT and drug delivery platforms gives a strong edge in the development and approval process for drug/device combination products, which are more challenging to develop than single drug products because it involves two different sets of regulatory guidelines and two different departments within the FDA, each with their own set of requirements.

- Wet AMD market in ophthalmology – Visudyne® is the only approved treatment for wet AMD on the market, and QLT currently has an edge on competitors in its relationship with the health care providers in this field, who are generally retinal specialists (QLT Inc., 2004, October 19).

These are the capabilities that QLT should leverage as much as possible to sustain future growth, because these are the areas in which QLT holds knowledge and experience beyond any other potential competitor. QLT must beware not to allow these capabilities to turn into core rigidities (Leonard, 1995), which will limit the company's outlook and prevent it from moving on to new technologies and innovations as necessary to drive future growth.

QLT also has the threshold capabilities that allow it to compete in the drug development industry, with functional groups to carry out all aspects of the drug development value chain except commercialization, as discussed in section 3.2. Some of the key enabling capabilities that have allowed QLT to succeed are listed below:

- Clinical development and regulatory affairs – QLT has received regulatory approval for all drugs submitted for marketing approval (QLT Inc., 2004, April 28). QLT has had experience planning clinical development programs in all of its therapeutic areas, and with regulatory submissions with a number of different divisions of the FDA.

- Fiscal responsibility – Few biotechnology companies have the record of sustained profitability that QLT has had for the past 5 years. Only half of the top 50 companies by market capitalization on the NASDAQ Biotechnology Index are profitable, and the number of profitable companies below the top 50 drops off drastically (Yahoo! Finance, 2005, January 27).

- Strategic partnership management – QLT has established commercial partnerships to successfully launch Visudyne®, Eligard® and generic dermatology products.

3.5.2 SWOT Analysis

A SWOT analysis summarizes the strengths and weaknesses in a firm's core capabilities and the opportunities and threats in the industry environment (Woodcock and Beamish, 2003). The SWOT analysis for QLT shown in Figure 5 builds upon the core capabilities identified in section 3.5.1.

Figure 5 SWOT Analysis of QLT

Strengths	Weaknesses
Technology	***Commercialization***
▪ PDT drug delivery platform	▪ Lack of sales infrastructure
▪ Atrigel® drug delivery platform	▪ Relies on partners for all marketed products
Pipeline	***Growth***
▪ Two product launches expected in 2005	▪ Limited focus on new markets
▪ 6 products in clinical development	▪ Pipeline gap after 2005
Intellectual Property	▪ Lack of diversification in pipeline may lead to further development of unpromising products
▪ Strong IP protection for its products, with a number of patents giving exclusivity for many years.	▪ Limited experience in managing significant growth (planning, implementation)
Financial	***Financial***
▪ Positive cash flow	▪ Primary revenue driver Visudyne® is facing significant competition
▪ Strong cash position	▪ Heavy reliance on partnerships which reduce profits
▪ Minimal debt	***Product Development***
▪ Diversified revenue streams (Visudyne®, Eligard® and dermatology products)	▪ Limited discovery capabilities
Product Development	▪ Current products are for relatively mature markets with established competition
▪ Preclinical and clinical R&D experience	***Strategic***
▪ Acquiring manufacturing experience through pilot manufacturing facility	▪ Second or later to approval of generic dermatology products resulting in low profits
Strategic	▪ Lack of presence in U.S. biotech cluster may limit some collaboration opportunities
▪ Key partnerships for commercialization (Novartis, Sanofi-Aventis, Sandoz, Astellas, Pfizer)	▪ Lack of strong corporate identity or presence in biotechnology industry due to partnering of commercial products
▪ Experience in 4 therapeutic areas (ocular, oncology, urology and dermatology)	
▪ Location in growing Vancouver biotech cluster	

Opportunities	Threats
Technology ▪ PDT in new therapeutic areas ▪ Atrigel® in new therapeutic areas ▪ Develop other proprietary drug delivery platforms ***Market*** ▪ Expand market for Visudyne® ▪ Expand market for Eligard® ▪ Expand generic dermatology products into new markets ***Commercialization*** ▪ Develop sales and commercial infrastructure to become FIPCO ▪ Self-market Aczone™ outside of U.S. (full rights retained in Europe, ROW) ▪ Self-market lemuteporfin for BPH (full rights retained) ▪ Self-market Atrigel®-Octreotide (full rights retained) ***Strategic*** ▪ Partnerships or acquisitions to acquire new technologies ▪ Partnerships to out-license technology platforms ▪ Offer CRO and CMO services to biotechnology companies	***Competitors*** ▪ Visudyne®: Macugen® launch expected Q1 2005; Lucentis in PIII clinical trials (Genentech); other wet AMD products in development ▪ Eligard®: Lupron on market (Abbott) ▪ Generic dermatology: many competitors due to lack of patent protection ▪ Acne market for Aczone™ has relatively high competition with many alternative products ▪ BPH market is changing rapidly, with many MIT's available and new drugs in development ***Product/Technology*** ▪ Drug/device combination may hinder uptake of PDT in new markets ▪ Diagnostics/genomics may change the nature of medical care ***Strategic*** ▪ Strong competition for strategic partnerships and promising late-stage technology ▪ FIPCO model not yet proven long-term for biotechnology industry ***Regulatory*** ▪ More stringent regulatory review due to recent product recalls (e.g. Vioxx®, Celebrex®) ▪ Reimbursement changes could directly affect profits

The threat to product revenues from changes in government reimbursement policies is a particularly important issue with Visudyne® and Eligard®. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 reduced the rate of reimbursement in the U.S. for certain drugs, including Visudyne®, to 85% of the April 1, 2003 average wholesale price, effective January 1, 2004 (QLT Inc., 2004, January). In March 2004, QLT received an exception to this act, allowing full reimbursement levels for 2004, but there was no commitment from the FDA to continue full reimbursement further (QLT Inc., 2004, March 16). In 2005, Visudyne® is reimbursed at Average Selling Price in 2004 plus 6%. Eligard® faces similar uncertainty as to reimbursement levels from the U.S. government. Lower reimbursement levels for patients could provide a disincentive for physicians carrying out these treatments to use these products, driving down their market share relative to competitor products that receive higher reimbursement levels, threatening QLT's income and profitability. Combined with the threat of competition for the wet

AMD market, these issues highlight the importance of QLT diversifying its sources of revenues and income through more commercial product offerings in relatively under-served markets.

Another major weakness in QLT's current situation is the multiple strategic partners for commercial products, which makes management of these alliances time-consuming and complex. Eligard® in particular has three different marketing partners for various regions, which increases the potential for conflicts in marketing strategies and decisions, leading to less than optimal product positioning and awareness and reduce its revenue potential for QLT.

Being the leading company in a cluster like Vancouver can have advantages and disadvantages for QLT. An advantage for QLT is readier access to in-license the best technology and research emerging from the local universities and early stage companies because of its financial resources and lack of competition. QLT may also have an easier time retaining key employees or attracting the best local talent to the company because of limited alternatives for local employment. The lack of other large biotechnology companies to learn from and model its growth on, however, can be an impediment to firm development. The Vancouver cluster may not be sufficiently mature to recruit many top people in the industry to the company from larger centres where there are more diverse job opportunities. The networking opportunities with other leading biotechnology and pharmaceutical companies are also very limited, which could hamper development of a strong reputation and high profile in the industry critical for improving business development prospects.

3.6 Gaps in Company Growth and Capabilities

The market capitalization required for QLT to become one of the top ten biotechnology companies worldwide by 2010 is about $5 billion in current terms (see Appendix 1), which would require a four to five-fold increase in QLT's valuation. At current P/E ratios, this market capitalization would require income of about $240 million. In 2010, our estimates show that QLT could earn $165 million if all of the current pipeline projects succeed and meet our assumptions for market size, market share, and growth (Appendix 14), which would merit a valuation of $3.5 billion using the current P/E ratio of 21. However, all of the current market leaders are expected to grow their earnings at least the same rate, if not faster than QLT, with the exception of Serono (Appendix 1, Earnings Growth % YOY). If we assume that the market leaders will grow at their current year over year earnings growth rate until 2010, the smallest market capitalization company will be Serono, at $8.9 billion. Our projected valuation for QLT in 2010 of $3.5 billion

is still well short of qualifying for the top 10 in 2010. QLT's income would need to be more than double our estimate of $165 million, to be at least $420 million in 2010 at current multiples, and to qualify for a top ten ranking among biotechnology companies. To make $420 million by 2010, QLT would need to be growing at an average rate of 59% per year.

The average year over year growth rate of the top ten biotech companies (Appendix 1) is 37%. We believe that if QLT was able to convince investors that it had the pipeline to drive an earnings growth rate of 37% between 2005 and 2010, QLT would be accorded a higher P/E ratio, similar to the market leaders. A 37% growth rate would give earnings of $220 million in 2010. The average P/E ratio for the market leaders excluding the outlier MedImmune and the unprofitable companies is 58. If QLT were able to obtain this P/E ratio, then the market capitalization in 2010 on earnings of $220 million would be about $12.8 billion, on track to being in the top ten.

3.6.1 Gaps in Growth

Our analysis of QLT's capability and product gaps as well as the recommended growth strategies are based on the above calculations, namely that QLT will need to grow at a 37% annualized average rate, and that 2010 earnings will therefore need to be approximately $220 million. We assume that with this growth rate the P/E ratio accorded by investors will increase to 58. Table 4 below summarizes the financial projections using three different growth rates: the optimistic rate of 21%, the risk-adjusted rate of 6%, and our recommended 37% growth rate target to reach the desired valuation, assuming constant net profit margin of 31%.

Table 4 Estimated Key Financial Measures and Targets

	Revenues ($US B)	Earnings ($US B)	P/E	Market Cap ($US B)
Current	0.174	0.054	21	1.1
Estimated 2010 at 26% growth	0.532	0.165	21	3.5
Estimated 2010 at 6% growth (risk adjusted)	0.288	0.089	21	1.9
Estimated 2010 at 37% growth	0.715	0.222	58	12.9

QLT is expected to launch the FDA-approved Eligard® 6-month release formulation for prostate cancer, and Aczone™ for acne treatment (once approval is obtained) in 2005. Following these products, Atrigel®-Octreotide, Lemuteporfin in BPH, Aczone™ for Rosacea and Atrigel® for bone regeneration are all expected to launch sometime in 2008-2009 if they are developed

successfully. According to these projections, QLT has no product launches in 2006 and 2007 because the company has no Phase III programs apart from the label expansion for Visudyne® in the occult form of AMD. The projected launches for the current clinical development products is also very aggressive, much faster than the industry average development times listed in section 2.1.1, Figure 1. We believe that there is a high risk that these products, even if developed successfully, will not meet their projected commercial launch targets in 2008-2009.

In contrast with an average of 7 commercial products and 13 clinical development programs for the top ten biotechnology companies (Appendix 2), QLT has 2 commercial products, neither of which the company owns the marketing rights to, and 5 clinical development programs, one of which is for a product licensed to a large pharmaceutical company[4]. This comparison highlights the shortfall of QLT's commercial diversification as well as the shortfall of its development pipeline relative to the top companies in the industry. The current pipeline is clearly inadequate to drive the growth rate and price to earnings ratio needed to achieve QLT's target valuation.

3.6.2 Gaps in Capabilities

While QLT has most of the business functions required to perform and compete successfully in the biotechnology industry, the company has some weaknesses in its capabilities. Our analysis of QLT's growth shortfalls above indicates a strong need for increased numbers of commercial products with greater revenue and income potential. In Table 5, we address the resource gaps by functional area, taking into consideration current advantages, required advantages, advantage gaps, and tactics and risks of filling the gaps (Woodcock and Beamish, 2003).

Table 5 Gap Analysis of QLT's Resources and Capabilities by Function

Function	Current Advantage	Required Advantage	Advantage Gap	Filling the Gaps: Tactics (and Risks)
Manufacturing	cGMP facility		Limited pilot manufacturing	Finish pilot facility (high cost)

[4] The Atrigel® platform is licensed to Pfizer for bone regeneration.

Function	Current Advantage	Required Advantage	Advantage Gap	Filling the Gaps: Tactics (and Risks)
Commercial	Marketing experience and market research	Full commercial infrastructure	Sales force	Develop sales force (high cost)
	2 major markets (wet AMD, prostate cancer)	Range of markets	Limited commercial products	Expand into new markets (high cost)
Financial	3 revenue streams	Retain more profits	Financial dependence	Commercialize in-house (high cost/limited experience)
Discovery	PDT/Eligard® discovery	Varied experience	Limited discovery	Develop new skills (high cost)
Strategic	Commercial partnerships	Network of partnerships	Limited in-licensing success	In/out-license technology (more players)
	3 drug delivery platforms	Innovative platforms for emerging biotechnology markets	Genomics/diagnostics/personalized medicine based technologies	Develop new drug delivery platforms (unproven therapeutic benefit)

This analysis combined with the SWOT analysis shows that QLT has been successful in leveraging its high value products and strategic alliances to achieve organizational growth to this stage. However, QLT's future growth is limited by its current dependence on strategic alliances for sales and marketing. These alliances are essential to firm growth early in its organizational development, but have many downsides as the firm reaches maturity (Oliver, 2001). Major downsides include reduced revenues through profit sharing, reduced interest in developing essential competencies, and unpredictable and opportunistic behaviour by the senior partner. These factors reiterate the importance of QLT being able to establish independence on their strategic marketing and sales partners by having full commercial capabilities in-house, including a sales force. QLT's current stage requires a shift from dependence on experienced partners for marketing to building these capabilities internally to be able to exploit their own assets fully.

Our analysis also highlights the limited experience with in-licensing late-stage technology and acting as a senior alliance partner, which will become more important for QLT in the future. We feel that the current manufacturing and discovery gaps do not pose a significant threat to QLT's growth objectives, and therefore will not focus any further on these areas. We expand on the strategies required to address each of the major capability gaps as well as the pipeline and products gaps in more detail in the following chapter.

3.7 Stakeholder Analysis

There are a number of stakeholders that have an interest in or influence over QLT's strategic direction and choices. Appendix 15 contains a chart listing the major stakeholders and their relative power and interest to influence QLT's strategies for growth. Those stakeholders that are higher along the power axis have a higher degree of influence over QLT, and stakeholders that are higher along the interest axis generally have a higher degree of impact from QLT's strategic choices. The stakeholders in the top right corner are those that have high power and high interest, and these are the major stakeholders that QLT needs to consider most when designing and implementing new strategies, including the Board of Directors, senior management, strategic partners, and institutional investors. Other major stakeholders that QLT must be aware of are employees, shareholders in general, strategic partners, customers (patients and health care providers), employees, health care payers, and regulatory agencies.

Any new strategy must consider implications for the major stakeholders to ensure its acceptance and feasibility. New strategies should also consider how to utilize some of the high interest or high power stakeholders to better advantage. In particular, the high power, low interest stakeholders like the FDA and Medicare can pose a significant threat to the success of QLT's products if they are not carefully managed. Early involvement and buy-in from these stakeholders is critical for getting marketing approval and sufficient reimbursement coverage to motivate sales of new and existing products.

Financial analyst opinion is also critical for getting favourable recommendations and stimulating investor interest in QLT's stocks, thereby increasing the company's valuation. Financial analysts must be carefully managed through timely and thorough corporate communications that give these analysts sufficient information to form the basis for positive recommendations. Although employees in general are not considered to be high power stakeholders, they are also essential to successful implementation and execution of corporate

strategies. Therefore, any new strategy must carefully consider the impact on employees, and their ability to execute it. There must be a reasonable fit between the existing core competencies of QLT employees and the competencies required for a new strategic direction.

3.8 Conclusions from Internal Analysis

QLT has had an impressive record of profitability based on revenue growth from Visudyne®, and evidence of strong financial management to sustain profitability. The company suffers from low valuation multiples relative to the top ten biotechnology companies, however, due to perceived limitations in its development pipeline for new products with high potential to drive revenue and income growth. Our analysis of QLT's pipeline shows that the number of commercial and development products and their revenue growth potential in the next five years are smaller than the average for the leading companies in the biotechnology industry. None of the products currently in the pipeline have the kind of blockbuster market potential that Visudyne® has. Furthermore, all of the commercial products and late stage development products have strategic partners for marketing, which limits their revenue potential for QLT and introduces uncertainty. When the pipeline potential is combined with the low probability of success and increasing competition in the biotechnology industry, QLT's future profitability is threatened by limited product diversification and limited focus on large markets with high unmet needs.

Analysis of QLT's capabilities combined with SWOT and gap analyses reveal that the company has unique strengths in drug delivery systems, combination products, and the wet AMD market. QLT also has excellent experience and capabilities in most of the important functions for drug development, and is particularly strong in clinical and regulatory development, fiscal management, and strategic partnership management. However, the gap in QLT's commercial capabilities is a major weakness that must be addressed before the company can achieve a higher growth potential that will support its corporate vision to be a top ten biotechnology company. We address this issue in detail in the following chapter.

4 GROWTH STRATEGY

In this chapter, we recommend growth strategies for QLT to achieve the corporate goal of becoming one of the top ten biotechnology companies by market capitalization by 2010. We specify growth objectives based on the analysis of QLT's industry and internal environment, and recommend the optimal business strategy and focus to meet these objectives. We further analyze the growth alternatives internally and externally. For external business development opportunities, we evaluate mergers and acquisitions, in-licensing, out-licensing, and partnering strategies. In addition, we evaluate potential business development deal candidates that can accelerate growth for QLT by 2010.

The market capitalization of a biotechnology company is comprised of two components: sales performance of commercial products and perceived value of pipeline (Wolpert, 2004). Therefore, to become one of the top ten biotechnology companies worldwide by market capitalization by 2010, QLT will need to maximize sales and revenues of commercial products, maximize success and minimize risk of the mid-term development pipeline, and accelerate preclinical development to build a robust pipeline by 2010. The perception of strong product platforms that can continue to fuel the development of many new product candidates in the future will also play an important role in high valuation. In addition, it is important that QLT brings the current development products to market faster with strong clinical results and a clear competitive advantage to obtain a large market share and enable attractive pricing, which will drive profits.

4.1 Growth Objectives

Based on the analysis in section 3.6.1, QLT needs to increase its growth rate, income, price/earnings (P/E) ratio, and ability to demonstrate continued growth at a high level. The recommended growth objectives to be in the top ten biotechnology companies by market capitalization are:

- Annualized average growth rate of 37%.
- Revenues growing to over $700 million by 2010.

- Profits growing to $220 million by 2010.

- Within the next two to three years, have at least three to four more Phase I/II products in clinical development with moderate to high revenue potential.

The rationale for the number of additional clinical development products is expanded upon below. In addition, QLT needs to target a P/E ratio of 58, and a market capitalization of at least $10 billion by 2010. To obtain this high P/E ratio and valuation in 2010, the company needs to create the perception of strong sustained growth for many years beyond that.

QLT currently has gaps in its development pipeline with no product launches scheduled in 2006 and 2007, apart from label expansion for Visudyne® in the occult form of AMD, which is not expected to have a large impact on revenues because this indication is already reimbursed by the U.S. Centers for Medicare and Medicaid. When the risk of the Phase I/II pipeline products is also taken into account, in order to meet the 37% annual growth target by 2010, QLT needs to increase the number of products in its development pipeline to reduce the gaps in commercial launches and new revenues, and find development products with much higher revenue potential. QLT can increase its development pipeline and revenue potential in two ways: accelerate preclinical development of current products, and acquire products externally.

The revenue shortfall between the target and the risk-adjusted scenarios shown in Table 4 in section 3.6.1 is approximately $450 million, which is the potential revenue from one blockbuster product with sales of $700 million at a 35% gross margin rate, or from 2 medium products with $230 million each in revenues, which equates to about $350 million in sales each. Moreover, for QLT to meet its target, the product must be in at least Phase I/II or preferably Phase III. Because of the high risk of failure of Phase I/II products, QLT should aim to have at least four more Phase I/II products in clinical development with modest potential, or two more blockbuster products within the next two to three years.

The high cost of developing such an extensive pipeline points to the need for the company to consider its financing strategy. QLT can use the earnings from its current products to fund the pipeline, which might result in a temporary decrease in valuation, depending on investor perception of the pipeline value versus the risk. However, 3 to 4 more development projects in Phase II to III over the next few years will potentially cost the company at least $100 million per year in development expenses, more than it is currently earning in revenues, or will be able to realistically earn by 2007. We address financing strategies in Chapter 5.

4.2 Business Strategy

QLT business strategy needs to be designed to maximize growth potential and meet the growth objectives outlined above. The core of this strategy will be to broaden the development pipeline to be able to make better choices for what to develop. A key part of this strategy will be to select the appropriate business model and business focus. QLT also needs to create sustainable advantage within a very competitive environment in the industry for business development deals to fill the pipeline, which requires creating a strong corporate brand identity that differentiates the company from other leading biotechnology companies. In this section, we address the business model, strategic positioning, and therapeutic areas that QLT should pursue to optimize its growth potential. For the purpose of this evaluation, we have assumed that QLT's goal is to remain an independent business.

QLT's high level strategy should include the following elements:

- Building new core capabilities
- Renewed focus on developing innovative and novel products for markets with high unmet medical needs
- Market products with sound reimbursement strategies

QLT's core capabilities in drug delivery systems, combination products, and wet AMD do not currently position the company to take advantage of emerging trends in biotechnology, including genomics, diagnostics, and personalized medicine. However, the drug delivery and combination product capabilities could provide an excellent complement for innovative methods of delivering therapies in these cutting edge areas. QLT should look for ways to leverage its strengths into these emerging areas over the next several years, which could be an important part of the company's identity as a leading biotechnology company rather than a specialty pharmaceutical company, which will increase its valuation.

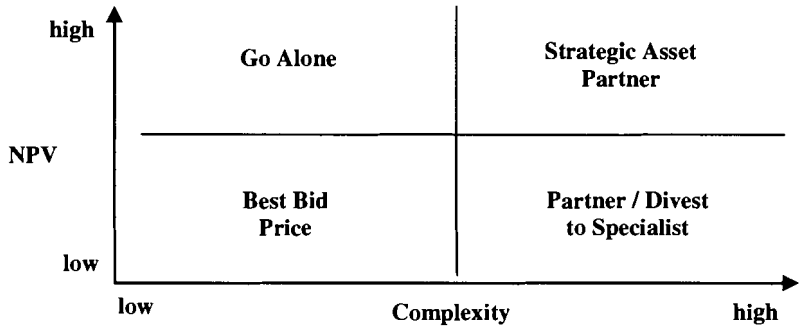
Focusing on developing novel products for markets with high unmet medical needs will also play a critical role in QLT's perception as a high growth, innovative company in the biotechnology sector. As shown in the SWOT analysis in section 3.5.2, all of the products in QLT's current development pipeline are pursuing relatively mature markets with established competitors. QLT established its reputation and its initial growth through a highly innovative product, Visudyne®, for a completely unmet market, wet AMD. To sustain the level of growth

provided by Visudyne®, QLT should focus on finding substantial markets with high unmet needs and minimal competition rather than depending on the incremental improvements provided by its current development products to drive future revenue and income growth. This strategy is being pursued by many large pharmaceutical and biotechnology companies with decreasing success, but QLT can leverage its drug delivery expertise to find new innovative solutions to challenging medical conditions. We expand on this concept for QLT's business focus in section 4.3 below.

As mentioned in the industry analysis and QLT's internal analysis, reimbursement of product costs to patients by government health care systems is a critical part of product acceptance and profitability. Any changes in current reimbursement policies can directly affect profits, and therefore impact financial performance and valuation. QLT needs to mitigate the threat of depleting revenues through reimbursement changes by developing new products with strong reimbursement strategies, which will require focusing on demonstrating excellent pharmacoeconomic benefit. The alternative is to select products with high patient motivation that bypass the reimbursement problem. We expand on this alternative in section 4.3.

To build a robust pipeline with numerous clinical development products, QLT needs to either internally develop the pipeline, in-license early stage technology, or acquire a company with many products in different phases of development. While we explore these internal and external opportunities later in this chapter, the following matrix of technical complexity versus net present value (NPV) is useful for determining what the best strategy is for building assets.

Figure 6 Assets: Complexity versus Net Present Value (NPV)



Source: Hall (2005), © Aspreva Pharmaceuticals Corporation, used with permission Aspreva Pharmaceuticals Corporation

Another factor that QLT needs to consider for continued growth is establishing a presence in a major U.S. biotechnology cluster, which seems to be a success factor for the top tier biotechnology companies, all of which are headquartered or have a regional office in one of the major biotechnology clusters (Appendix 2). The options are to open an office independently, or to consider a business combination with a company located in a top cluster, which would give QLT access to the networking opportunities and cross-fertilization of ideas and human resources that occur more effectively in clusters. Vancouver has a growing cluster with a number of promising biotechnology companies, and QLT does not need to relocate its headquarters at this time. Being a senior member in the Vancouver biotechnology cluster gives QLT good access to the strong patenting and technology development taking place, particularly due to the productive efforts of the University of British Columbia and affiliated researchers. However, if the growth of the cluster were to stagnate from failure of late stage companies to successfully commercialize their products, then QLT will need to consider relocating at that time.

4.2.1 Business Model

From an organizational perspective, growth and higher valuation require that QLT make the transition from dependence on its strategic alliances for marketing its commercial products, to maintaining control over the highest value part of the value chain, commercialization. All of the top ten market capitalization companies in the biotechnology industry follow the FIPCO business model, which indicates that valuation is related to the degree of integration. Most of these companies had a similar history to QLT: early strategic alliances with large pharmaceutical companies that supported their initial product launches with financial investment and marketing expertise (Oliver, 2001). As these companies established sufficient revenues, they were able to make the transition building their own commercial and production infrastructure, maximizing their profits and their learning from these activities. Their experience was then transferred to building further networks of partnerships, mainly with junior biotechnology companies that needed their marketing expertise. QLT must make the same step towards full integration, to maintain control over its assets and be positioned for the higher growth and the higher valuation needed to compete with and be ranked among the top ten biotechnology companies.

QLT needs to add commercial sales capability and infrastructure to become more integrated along the value chain in order to extract maximum value from its commercial and development products. Commercializing products in-house will allow the company to retain a higher percentage of product revenues than partnering. Adding commercial capability is also

critical to the company's growth through filling the product pipeline, because potential business development partners are only likely to partner or out-license a late-stage development candidate to a company with full commercial capabilities, including sales and marketing.

QLT can consider growing a commercial infrastructure internally if there are a number of products with retained commercialization rights concentrated in a therapeutic area, or a product with very large market potential, when these pipeline products get closer to market and there is greater certainty about their efficacy and their market potential. There are two other major routes to adding commercial infrastructure in the near-term: out-sourcing and acquisition. Either of these options will only be necessary if QLT is able to expand its development pipeline with products that are closer to market than the current pipeline. Out-sourcing of sales to a contract sales organization should be considered if there is only a single commercial product in a therapeutic area with a small to moderate market for a specific physician group, for example, oncologists specializing in gastroenterology. Acquisition of a company with sales capability should only be carried out if the deal fills other gaps in QLT's growth or capabilities. We evaluate this option in further detail in Section 4.5.

4.2.2 Business Focus

As described in section 2.4.1, there are a number of biotechnology companies that have the hybrid business model, combining a platform or tool based approach with product development. QLT needs to define a strategic business focus and strong positioning statement that differentiates the company from other biotechnology companies in order to become a market leader. A differentiated business focus and positioning, or a strong corporate brand identity, should increase QLT's profile in the industry, making it easier to carry out business development deals and increase investor interest in the company. The business focus should be based on its core capabilities in targeted drug delivery systems and combination products, with the addition of commercial capabilities, which will differentiate its brand from the rest of the top biotechnology companies, and the rest of the hybrid business model companies. QLT should strive to become known as the partner of choice for any researcher or company who is developing a novel product that uses a drug delivery system, whether formulation-based, device-based, or any other innovative technology. This partnering can be either to bring a new product in-house or to out-license a drug delivery platform to companies that need a better technology.

QLT's current positioning statement from their corporate website is as follows:

> QLT is a global biopharmaceutical company specializing in developing treatments for cancer, eye diseases and dermatological and urological conditions. We have combined our expertise in the discovery, development, commercialization and manufacture of innovative drug therapies with our unique technology platforms to create highly successful products such as Visudyne® and Eligard®.

We evaluated the corporate overview/positioning statements of the current top ten biotechnology companies, shown in Appendix 2. The majority of these positioning statements give the high level business focus and strategic position first, and then follow with the specific therapeutic areas that the company focuses on. These statements also tend to be forward-looking and medical need or patient based. Based on our recommendation to create a more differentiated and stronger positioning statement, we suggest focusing on the drug delivery platforms first and the therapeutic areas second. For example:

> QLT is a global biopharmaceutical company focusing on the discovery, development, commercialization and manufacture of innovative drug therapies, using unique drug delivery technologies to create highly successful products such as Visudyne® and Eligard®. We specialize in developing treatments for cancer, eye diseases and dermatological and urological conditions with high unmet needs.

Based on this revised positioning statement, QLT should continue focusing on creating innovative drug delivery technologies that will each provide a strong platform for developing therapies for multiple disease indications, thereby taking advantage of economies of scale and scope in development and manufacturing. These innovative technologies may also provide the opportunity to solve unmet needs in challenging medical indications that other companies have failed at, like the company did with Visudyne®. In particular, QLT should consider developing capabilities in targeted drug delivery technologies that will position the company to take advantage of some of the growing trends in biotechnology, such as genomics, diagnostics, and personalized medicine. Platforms for the delivery of gene-based or anti-sense oligonucleotide based therapeutics may be a reasonable longer term area for QLT to investigate. Any work with novel technology platforms should be carried out with an initial focus on QLT's current therapeutic areas.

4.2.3 Therapeutic Areas

The therapeutic areas that QLT should focus on for new development products are those that will provide the best opportunity for building a commercial sales force as well as building on

the existing knowledge and capabilities. Dermatology and urology provide the strongest opportunities for building a sales force in house, because the company has multiple products in the market or in the development pipeline for these therapeutic areas. Eye disease is also an important area for QLT to focus on because of the deep knowledge and experience in development and marketing gained from Visudyne®. However, for eye disease, QLT must consider products with large market potential in order to justify building a sales force, because Visudyne® is partnered with Novartis. There is little opportunity for QLT to develop sales capability from Visudyne® unless QLT can re-negotiate the agreement with Novartis, which we believe is unlikely or unfeasible because of the value this product brings to Novartis, thus requiring a prohibitively large payment to buy back the promotion rights. QLT also has strong experience in developing oncology products, and should continue to focus on this therapeutic area, ideally with a concentration in prostate cancer because of its experience with Eligard®, and gastroenterology because of Atrigel®-Octreotide and the need to build a specialist sales force within the diverse oncology market.

While we believe that QLT should continue to focus its primary efforts on its current therapeutic areas, QLT should also remain open to opportunities outside of the current therapeutic areas that can capitalize on its core capabilities in drug/device combinations, formulation platforms, and PDT. Particularly attractive opportunities are those that will allow entry into new markets with existing products or platforms, using the market development growth strategy that we found was lacking in our analysis in Section 3.3 (Table 3). QLT should spend some time and effort investigating these opportunities. Because of the need to focus on commercialization, QLT should ensure that these new areas have large markets and/or multiple applications of platforms or drugs.

4.3 Internal Opportunities

To achieve its growth objectives, QLT should exploit a number of internal opportunities for expanding the pipeline. The major internal growth opportunities involve maximizing the value of their platforms and their existing products. QLT can also employ development strategies that will accelerate product timelines, maximize clinical and regulatory success of these products, and create a robust pipeline of clinical products by 2010.

QLT's primary internal focus over the next several years should be to ensure the rapid and successful advancement of its current development pipeline products Lemuteporfin in BPH, Aczone™ in Rosacea, and Atrigel®-Octreotide, to achieve commercialization and revenues from

these products as soon as possible. The other major internal focus should be on accelerating the advancement of preclinical research candidates into clinical phases to ensure that most preclinical programs are in development by 2010.

To maximize the value of existing drug delivery technologies, QLT should focus on developing new indications for PDT, SMP™ and Atrigel® within the core therapeutic areas discussed in section 4.2.3. To develop new PDT indications, QLT should consider alternative methods of delivering light to activate its current photosensitizer in development, lemuteporfin. In addition, QLT should consider alternative photosensitizers that might have better pharmacokinetics and improved target drug activity. PDT is also a good candidate for topical delivery through the skin, and the company should work on improving formulations for topical delivery of photosensitizers. For the SMP™ and Atrigel® platforms, QLT should continue to seek new molecules that can be transported through these delivery platforms to expand their scope and use. QLT should also maximize the potential of these platforms by continuing to reformulate oral generic products for topical delivery for indications with high unmet needs, as was the case with Aczone™ using the Atrigel® platform. QLT can then create strong intellectual property positions on these reformulated products, which leads to higher value and revenue potential. To become a partner of choice for innovative therapies that involve drug delivery technologies, QLT will need to further maximize the value of their existing platform technologies to demonstrate superior capabilities in drug delivery mechanisms.

QLT must also maximize the value of existing products to continue expanding their pipeline and meet their growth objectives. As the growth matrix identified in section 3.3, QLT must establish new markets with different patient populations for existing products to increase market development and growth within its core therapeutic areas. In particular, QLT should look for new indications with its current commercial products, Atrigel® with Eligard® and Aczone™ because of prolonged patent life. QLT can also look for other new indications for PDT using lemuteporfin because patent coverage extends until 2017/2018. QLT should remain focused on these commercial products for new market opportunities rather than generic dermatology products, due to their low profit margins and limited opportunity to grow QLT's income.

QLT should also direct some research effort towards discovering new platform technologies, as these can be important for growing core capabilities. The company needs to keep in mind, however, that the perceived value of the pipeline is largely dependent on the progress of clinical development, and that any discovery work at this stage is unlikely to produce a clinical development candidate by 2010. This research could provide the basis for partnering or in-

licensing, however, and could also fuel positive perception of QLT as a dynamic, innovative company with strong pipeline potential.

Reimbursement strategies are important for sustained growth and revenues, and QLT must continually assess the pharmacoeconomic benefits of existing and new products. Government agencies such as Medicare must be involved during product development and commercialization in order to ensure attractive reimbursement coverage for existing and new products. QLT cannot afford to wait until a product is ready for commercialization before seeking reimbursement coverage because of the increased pricing pressure on reimbursed products (see section 2.3.1). One way to mitigate the threat of reimbursement issues is to market products to motivated patients that are willing to pay for their own treatments. Lifestyle drugs, especially in dermatology, can be very attractive patient-payer markets because government reimbursement is not an issue. An example of the significant revenue potential for these therapies is Botox®, a lifestyle dermatology drug with estimated 2005 sales of $800 - $840 million (Allergan Inc., 2005).

QLT should also take a continuous improvement approach towards development programs and seek opportunities to improve processes as products move through the phases of drug development. Projects that are unprofitable or have low revenue potentials should be killed early in the development stage to keep unrecoverable losses to a minimum and focus resources on the most promising projects.

4.4 External Opportunities

To meet QLT's growth objectives, the company must look to external opportunities for building a development pipeline to fuel earnings and valuation growth, because of the gap in the internal pipeline and the risk of relying on the current internal opportunities alone. QLT's limited discovery capabilities also points to the need for the company to acquire, in-license or partner for new products or platforms from external sources. The company also needs to maximize the value of its existing products and platforms by looking for out-licensing opportunities that do not compete with its internal pipeline.

4.4.1 Mergers and Acquisitions

Companies could be potential merger and acquisition (M&A) targets for QLT for a number of reasons. Financing needs are high on the list of reasons why companies might engage

in an M&A (Danzon et al, 2004). A company like QLT with plenty of cash but limited pipeline products tend to be attractive partners for companies like Atrix, which need additional infusions of cash to pay for their pipeline development. Filling capability gaps, such as marketing and manufacturing, is also a compelling reason for M&A activity. Combining capabilities to reach critical mass and achieve economies of scale can also stimulate mergers between two medium-sized companies, which can result in a large market capitalization company that has the leverage to carry out more extensive research, development, and business development activities.

QLT needs to consider carrying out a merger or acquisition with a company with sales capability and commercial infrastructure, or the opportunity to build one in the very near term, because of the need to be able to offer this capability to other in-licensing or partnering prospects. However, a merger or acquisition should only be carried out if the business combination fills other gaps in QLT's growth, namely the need for more pipeline products in its core therapeutic areas. Ideally, an M&A candidate will be profitable, have a strong development pipeline that complement QLT's therapeutic areas, and have drug delivery platforms and technologies. In order to keep earnings strong and have access to near-term revenues, QLT ideally needs to acquire a profitable or near-profitable company with a robust pipeline, similar to the characteristics Atrix. This could be accomplished through a merger of equals or acquisition of a smaller market capitalization company. A merger or acquisition target should have at least three superior products in their clinical pipeline, have revenues and a commercial sales force in one therapeutic area that fits with QLT's current therapeutic focus.

Mergers and acquisitions (M&As) can build value if the combined business fills strategic gaps in capabilities and assets, and leads to earnings accretion rather than diluting shareholder value. However, because of the number of companies in the biotechnology industry that are unprofitable, it is difficult for a profitable company like QLT to find M&A deals that lead to earnings growth in the near-term. The desire to remain independent will also limit the size of deals that QLT can undertake, and still remain the controlling entity. The corporate culture and vision also need to fit for a business combination to be successful. One of the major challenge to completing an M&A is to provide the right incentives to the CEO of the acquired company, who will likely lose their job.

Integrating two businesses following an M&A can be extremely challenging. Companies can have large differences in their business practices and organizational configuration and structure, which can provide a hurdle for successful integration. Major integration issues can span

all business areas, from business processes such as strategic planning, human resource management, and project management, to technology systems such as financial accounting. The change and uncertainty inherent in M&As can also be very challenging for individual employees, unless the process is managed very effectively by senior management. QLT is still completing integration following its recent merger with Atrix, and needs to be cautious about involving the organization in another round of integration and change in the near term. Therefore, we reiterate the importance of QLT undertaking another business combination only if a deal meets multiple strategic gaps in QLT's capabilities, especially commercial infrastructure, filling development pipeline and revenue gaps, and strengthening QLT's core capabilities in drug delivery technology.

Despite these precautions, because of the importance of this strategy to QLT's sustained growth, we evaluate potential acquisition targets in detail in section 4.5 later in this chapter. We also provide recommendations for mitigating any potential downsides to business integration in the following chapter, in section 5.2.3.

For QLT to execute an M&A deal, the company should consider following this standard sequence of steps required to carry out the deal (Doyon, E., 2003):

- Target the acquisition/merger candidates
- Evaluate internal capabilities and consider appointing advisor(s)
- Valuate the target and identify potential synergies
- Structure the transaction
- Arrange for appropriate financing
- Carry out a due diligence process
- Carry out integration planning (including key employee retention plan)

Post-acquisition or merger, the following steps must be carried out (Doyon, E., 2003):

- Rapidly execute integration and implement decisions
- Assign responsibilities to realize synergies
- Measure performance relative to initial objectives (quantitative and qualitative)

4.4.2 Product In-licensing

In-licensing is the optimal way for QLT to fill specific gaps in its development pipeline, allowing the company to choose the most promising products with the best fit to QLT's portfolio. QLT should focus on acquiring development products with high revenue and income potential in order to achieve high growth targets. Because the costs of developing a product are similar

whether the product has a medium or large market potential, returns on the investment can be maximized by selecting a high potential candidate. In-licensing is less expensive in the short term than an M&A, especially if payments are tied to achievement of specific development milestones. Bringing a product internally allows for more control over its development, with none of the organizational issues associated with integration of an acquisition, or the strategic issues associated with collaboration.

Because QLT needs to fill its revenue growth gaps in the 2006 to 2009 timeframe, the company should carry out a combination of late-stage deals and high potential preclinical stage deals to maximize growth. Late stage deals should be completing Phase IIb or further along the development path, to provide near-term revenues while minimizing the risk of failure, which is still high for early Phase II products. To bring more products into its pipeline, QLT will need to strengthen its ability to compete for promising late-stage technologies that are available for in-licensing. As the number of new drug approvals decreases among pharmaceutical companies (Burrill, 2005), there is more competition for in-licensing technologies, therefore QLT will need to remain competitive among pharmaceutical and biotechnology companies to acquire new technologies. In-licensing opportunities are highly dependent on degree of fit with existing capabilities.

In-licensing a late stage product will only be feasible if QLT is able to offer full commercial capabilities, because licensors are generally looking for royalties from licensed products, and will want to choose a licensee that will maximize revenues. QLT needs to either build a sales force, or acquire one before completing a late-stage in-licensing deal, or at the very least be able to show its potential partners a strong commitment to building the commercial infrastructure and convince them of their capability to manage a sales force. Out-sourcing of sales to a contract sales organization is unlikely to be satisfactory to a licensor, because of the added overhead costs from contracting, and the perception of less control. There is heavy competition from large pharmaceutical and biotechnology companies for in-licensing the most promising products, and QLT needs to be able to provide an advantage over other potential licensees. Because QLT cannot offer an experienced sales force, QLT will need to offer financial advantage, such as higher upfront, milestone and royalty payments, or experience advantages in other areas such as the retinal specialist or urology markets, or combination product regulatory approvals. QLT may need to offer a slight financial advantage over larger biotechnology companies with established sales capabilities, but offering too much financial advantage is not

advisable because of the dilution of the value of the deal to QLT. Therefore we recommend that QLT focus its in-licensing efforts on areas in which it can offer experience advantages.

Based on QLT's experience and core capabilities, the company should focus its late stage in-licensing efforts on three major areas: ophthalmology, dermatology, prostate cancer/urology. The following table outlines our recommended near term in-licensing strategy for QLT.

Table 6 Recommended Product In-licensing Characteristics

Feature	Recommended	Rationale
Therapeutic Area/Indication	Eye disease, especially AMD	Build on core capabilities, leverage retinal specialist relationship
	Dermatology	Leverage opportunity to build dermatology sales force in Europe for Aczone™
	Prostate cancer	Build on opportunity to build urology sales force for BPH, leverage relationship and experience from Eligard®
Number of Deals	3 products total	Number required to fill revenue gaps at reasonable market size
Probability of Success	>60%	Probability needed to meet growth targets
Product Type	Drug delivery or combination product	Build on core capabilities and experience
Market	High unmet need	Build QLT's reputation for innovation
Sales Potential	$300-400 million annual peak sales for each product	Sales needed to achieve growth targets, accounting for risk of failure
Revenue Potential	$250 million annually per product	Revenue needed to achieve growth targets, accounting for risk of failure
Time to Market	<4 years	Timeline required to achieve target growth/valuation by 2010.

In addition to late stage in-licensing, QLT should consider in-licensing earlier stage products, preferably preclinical. The best stage for in-licensing in new products is preclinical,

because deals cost much less at this stage, even after accounting for the high risk of failure (Windhover, 2002). QLT's early stage in-licensing strategy should focus on products with novel drug delivery technology or platforms, to build on QLT's capability and reputation as a drug delivery specialist. Ideally, QLT would in-license the rights to the entire platform, and then develop products using that technology within its core therapeutic areas. The company could then obtain additional revenues by out-licensing rights to indications outside of its therapeutic areas. QLT also needs to consider in-licensing specific new molecules at the preclinical or development stage that could be re-formulated more effectively in its existing drug delivery platforms, as mentioned in section 4.3.

4.4.3 Out-licensing

QLT should continue to out-license its drug delivery platforms for indications outside of its core therapeutic areas, to obtain additional revenues while avoiding the threat of competition. However, out-licensing should not play a large role in QLT's growth strategy. Out-licensing does not have the revenue growth potential of developing products internally, but this strategy is a low risk way to obtain revenues in areas that QLT has no expertise or intention to pursue. The platforms that QLT can consider out-licensing are Atrigel® and SMP™, and other delivery platforms the company might develop in the near term. QLT should not out-license its PDT platform, because this is an essential part of QLT's reputation as a world leader in this field, and could result in giving away core knowledge and capabilities to a potential competitor.

QLT can also consider indication splitting deals for current or new products, if there is an appropriate indication for a product outside of QLT's therapeutic areas. In this case, a different strategic partner can be chosen for each indication that QLT does not want to pursue, leading to increased value by maximizing the performance of a single product. Again, QLT should only consider this kind of deal for products that will not be giving away core capability advantages, for example with some of the ILK products currently in the preclinical stage.

4.4.4 Collaboration and Partnerships

Collaborations can be carried out with QLT as the lead partner, or as the less experienced partner. QLT currently has partnerships with a number of larger pharmaceutical companies, in which QLT has developed the product, and a larger partner markets the product. While QLT needs to maintain good relationships with its current partners, such partnerships should become less important to QLT's future growth, as the company endeavours to become a FIPCO.

Collaborations with QLT as the lead partner with companies with promising development products, however, should be an important long-term growth strategy for QLT. For this strategy to be feasible, QLT again must be able to provide commercial capability. Most companies will be looking for strategic alliances with senior companies that have a proven development and commercial track record, to enable their own growth and learning. Once a sales force in place, collaborations could play a larger role in QLT's overall strategy for diversifying and growing its revenues.

Collaborations generally involve lower upfront payments than in-licensing, and higher profit-sharing with the partner, therefore these types of deals can defer financial risk and investment until there is greater technology and market certainty for a product. Deferring financial payment can be an effective strategy to manage cash flow and maintain higher income levels. However, collaborations can be more challenging to manage than in-licensing deals because of the greater degree of agreement needed on all aspects of product development and marketing strategy. We recommend that QLT consider entering into collaborations with junior biotechnology companies for development products with the similar product characteristics to those outlined in Table 8 when a sales force is in place, ideally within the next 2-3 years. This could be a relatively low cost way to drive the perception of high growth potential, leading to a higher valuation. QLT should target having several collaborations in place for products in the clinical development phase by 2010. These partnered products could be earlier stage than our recommended Phase IIb for in-licensing candidates because of the deferred financial risk.

4.5 Deal Candidate Evaluation

To meet the aggressive growth objectives discussed in section 4.1 and sustain growth, QLT must consider a merger and acquisition (M&A) strategy (see section 4.4.1). Suitable M&A candidates should ideally have one or more commercial products to drive near-term growth, and have a robust pipeline to increase QLT's perceived value and ability to sustain growth. Ideally, the deal candidate should also offer a commercial sales force in at least one of QLT's therapeutic areas. Financial factors are equally important, and suitable candidates will be positioned to earn substantial revenues by 2010, and be accretive to the value of QLT's shares. The candidate should have good fit with QLT's values and growth objectives, and be complementary to QLT's structure and organization. In particular, the senior management of the candidate must be open to QLT becoming the lead organization, as QLT CEO Paul Hastings is still in the prime of his

career, and we assume that he will not support any M&A that would not result in his leadership of the combined organization.

In this section, we evaluate potential acquisition targets that provide QLT with immediate growth opportunities. We describe the methods we used to screen potential deal candidates, then follow with a more in-depth analysis of the financial feasibility and product and pipeline compatibility for each company. We end this section with an overall ranking of the deal candidates based on an evaluation of how well they fill the gaps in QLT's growth and capabilities.

4.5.1 Screening Methodology

In order to select potential merger and acquisition (M&A) targets for QLT, we screened biotechnology and biopharmaceutical companies listed on the NASDAQ exchange using the following filters. The first filter we used was a market capitalization between $100 million and $1.5 billion, as a reasonable range of valuation for QLT to be the lead organization or at least an equal in an M&A[5]. The next filter was for profitability, and then the final filter was for compatibility of business focus and therapeutic area concentration, and ideally for a commercial sales force. This screen yielded 2 potential acquisition targets out of 522 companies in the Biotechnology/Drugs industry category, which we felt was an insufficient number for this analysis. We then looked at unprofitable companies in $100 million and $1.5 billion market capitalization range, then again filtered for business focus and therapeutic area fit. Once we had narrowed down the range of companies to those in QLT's therapeutic areas, we looked more specifically for companies with at least one development product in Phase III or later with all commercial rights retained, because these products provide the opportunity to build a sales force and fill QLT's revenue growth gap within the next 2-3 years. We narrowed the list further by selecting only companies with 3 or more products at the clinical stage or later with retained rights, which created a shortlist of 10 companies. We chose five companies from this shortlist, based on closest pipeline to commercialization, for further analysis in the following section.

4.5.2 In-depth Analysis of Top Deal Candidates

The five companies chosen for further analysis are summarized in Table 7. Each company is categorized in terms of suitability, acceptability and feasibility according to the

[5] All financial values and data used in screening were derived from Yahoo! Finance (2005, February), unless otherwise noted.

following definitions: suitability of therapeutic areas and commercial sales force, acceptability of the commercial products and development pipeline and feasibility of a deal in terms of revenues and valuation. Each company could potentially bring unique characteristics to QLT's established business. A brief company background and more in-depth analysis of the financial feasibility and product and pipeline compatibility for each deal are presented in the following sections. Financial feasibility calculations are based on the assumptions listed in Appendix 16, and are for preliminary screening purposes only, rather than a recommendation. We discuss the financing strategy for recommended deals in more detail in Chapter 5.

Table 7 Top M&A Deal Candidates

Company	Suitability		Acceptability		Feasibility	
	TAs	Sales Force	Commer-cial products (# and TA)	Pipeline (# and phase)	Revenues (US $M)	Valuation (US $M)
Connetics Corporation	D, DD	D	4 D	2 NDA, 1 PIII	144	866
Ligand Pharmaceuticals	C, D	C, D	1 Pain, 2 C, 1 D	1 PIII, 2 PII	127 (9 months)	798
Cell Therapeutics	C, DD	C	1 C	2 PIII, 2 PII	21.5	587
Barrier Therapeutics	D	D	1 D	1 NDA, 2 PIII, 4 PI/II	0.5 (9 months)	402
Cell Genesys	C - PC			1 PIII, 3 PII, 2 PI/II	11	280

Legend:
TAs = Therapeutic Areas
D= Dermatology
DD = Drug Delivery
C = Cancer
PC = Prostate Cancer
P = Clinical Phase
Source: Yahoo! Finance, Industry Centre (2005, February)

4.5.2.1 Connetics Corporation

Connetics Corporation (NASDAQ: CNCT) is a specialty pharmaceutical company focused on development and commercialization of innovative products in dermatology

(Connetics Corporation, 2005[6]). The company has innovative delivery systems including foam technology for enhancing drug delivery to the skin. Connetics has its head office in Palo Alto, California, a subsidiary in Australia focused on research and innovation of new delivery technologies, and a U.S. field-based sales force in dermatology. Thomas Wiggans, age 52, is Connetics President, CEO and a director on its Board, and has held this position since 1994. Prior to this, he was President of the U.S. Pharmaceutical operations of the Ares-Serono group.

4.5.2.1.1 Financial Feasibility

With a current market capitalization of $866 million and a 28% deal premium, it would cost QLT $1.1 billion to purchase Connetics, making this the most expensive candidate out of those being evaluated. Since QLT had $380 million in cash as of December 31, 2004, the maximum cash that can be offered is $300 million, or 27% of the purchase price. The remainder of the purchase would require the issuance of 60.1 million common shares at $13.46 per share (based on QLT's current share price) for a total of $809.2 million in stock. The high valuation of Connetics relative to QLT will make a merger more feasible than an outright acquisition, which will require careful negotiation of terms by QLT's senior management in order to retain overall control over the combined business.

The estimated financials for Connetics to 2010 are summarized in Appendix 17, as well as combined company financials. The major attraction of this deal is the profitability of the company, which leads to near term and long-term gains for the combined company. Using the assumptions listed in Appendix 16, the combined company (QLT and Connetics) net income in 2010 is estimated at $258 million with an annualized average 5 year growth rate of 25% and EPS of $1.63 (158,118,158 shares outstanding). The acquisition would initially dilute the value of QLT's shares by 21% in 2005, and then be increasingly accretive to value of QLT's shares by 17% to 79% from 2006 to 2010. Although the net income in 2010 for the combined company is over the target range of $220 million, the growth rate is short of the 37% goal set to reach a top ten biotechnology valuation by 2010, and therefore the P/E ratio accorded by financial analysts is likely to be less than the average top tier biotechnology company of 58. The P/E ratio will likely be closer to QLT and Connetics current range of 21 and 47 respectively, leading to a valuation between $5.4 billion and $12.1 billion, which may be enough to achieve a top ten ranking.

[6] All Connetics Corporation background information was obtained from their corporate website (Connetics Corporation, 2005).

4.5.2.1.2 Product and Pipeline Compatibility

Connetics products are all focused on the dermatology market, in a number of different indications. The company has four commercial products currently on the market, and three products in development, two of which have completed clinical trials and have had been submitted to the FDA for marketing approval. Appendix 17 summarizes the commercial and development product characteristics and markets. Total 2004 product revenues were $142 million, while 2005 revenues are projected to be $190 to $200 million, for a 32% to 39% growth rate. Connetics is working on developing products using two additional delivery platforms: an aerosol foam, and a polymer gel-matrix system for controlled release of drug substances.

4.5.2.2 Ligand Pharmaceuticals

Ligand Pharmaceuticals (NASDAQ: LGND) is a San Diego based specialty pharmaceutical company focusing on innovative small molecule drugs for oncology and dermatology[7]. The company has strong research and development programs and expertise in gene transcription technology, hormone and hormone related drugs, and natural intracellular receptor-mediated mechanisms that regulate cellular activity (Ligand Pharmaceuticals, 2005). Ligand has a cancer and dermatology sales force in the United States and has co-promotion rights for its lead pain product. David Robinson, age 55, is Chairman of the Board, and has been President and CEO since 1991, prior to which he was Chief Operating Officer of pharmaceutical company Erbamont. He is also chair of the U.S. based Biotechnology Industry Organization.

4.5.2.2.1 Financial Feasibility

With a current market capitalization of $798 million and a 28% deal premium, it would cost QLT $1 billion to purchase Ligand. QLT can afford to offer 29% of the purchase price in cash, or $296 million. The remainder of the purchase would require the issuance of 53.9 million common shares at $13.46 per share (based on QLT's current share price) for a total of $725.2 million in stock.

The estimated financials for Ligand to 2010 and the combined companies are summarized in Appendix 18. Ligand is expecting to be profitable in the very near term and going forward, due to healthy and growing revenues from its commercial products. Using the

[7] All Ligand Pharmaceuticals background information was obtained from their corporate website (Ligand Pharmaceuticals, 2005).

assumptions listed in Appendix 16, the combined company (QLT and Ligand) net income in 2010 is estimated at $320.5 million with an annualized average 5 year growth rate of 34% and EPS of $2.11 (151,879,822 shares outstanding). The acquisition would initially dilute the value of QLT's shares by 24% in 2005 and 18% in 2006, and then be increasingly accretive to value of QLT's shares by 35% to 132% from 2007 to 2010. The growth rate and earnings of the combined company meet the growth objectives that we set for QLT, and would likely vault it into the top ten rank of biotechnology companies by market capitalization. At a P/E ratio of 58, the valuation could be $18.6 billion in 2010.

The high valuation of Ligand Pharmaceuticals relative to QLT also makes a merger more feasible for this deal than an outright acquisition, which will require careful negotiation for control of the combined business. However, Ligand's current valuation is low relative to its pipeline and earnings potential, due to management's record of missing the growth and earnings expectations they have set (Ashton, 2004). While missing revenue targets raises questions about the company's sales and marketing capability, it also provides the opportunity to potentially acquire shares in the company at an attractive price, and then build value through careful financial management.

4.5.2.2.2 Product and Pipeline Compatibility

Ligand currently has four commercial products on the market, and three products in the clinical development stage. Ligand's largest sales are from Avinza, a pain product, for which the company shares co-promotion rights in the U.S. The remaining three products are for skin cancer and dermatology, and have had limited sales in the past year. The company's most advanced development candidate is for non-small cell lung cancer, and the Phase III clinical trials are expected to be completed in March 2005. The other two development products are in Phase II, and are for cancer indications as well. Details on each of these products are provided in Appendix 18. The company also has numerous other products in earlier stages of research and development.

4.5.2.3 Cell Therapeutics Inc.

Cell Therapeutics Inc. (NASDAQ: CTIC) is a Seattle based biopharmaceutical company focused on cancer therapies. The company has a cancer sales force in the U.S. and Europe (Cell Therapeutics, Inc., 2005)[8]. Cell Therapeutics recently merged with an Italian company,

[8] All Cell Therapeutics background information was obtained from the corporate website (Cell Therapeutics, 2005).

Novuspharma, bringing an additional Phase III product into its pipeline. Dr. James Bianco, 47, has been the President and CEO since 1991, and is the principal founder of the company.

4.5.2.3.1 Financial Feasibility

With a market capitalization of $587 million and a 28% deal premium, it would cost QLT $751 million to purchase Cell Therapeutics. The maximum cash that QLT can offer is 39% of the purchase price, or $293 million. The remainder of the purchase would require the issuance of 34.1 million common shares at $13.46 per share (based on QLT's current share price) for a total of $458.3 million in stock.

The estimated financials for Cell Therapeutics to 2010 and the combined companies are summarized in Appendix 19. Using the assumptions listed in Appendix 16, the combined company (QLT and Cell Therapeutics) net income in 2010 is estimated at $404.7 million with an annualized average 5 year growth rate of 130% and EPS of $3.06 (132,051,233 shares outstanding). The acquisition would initially dilute the value of QLT's shares by 163% in 2005 and 82% in 2006, and then be increasingly accretive to value of QLT's shares by 22% to 237% from 2007 to 2010. The advantage of this deal is very high growth and earnings potential by 2010. At a P/E ratio of 58, the combined company's valuation could be $23.5 billion, well within the range needed to be in the top ten rank of biotechnology companies. In the short term, however, QLT would become unprofitable due to the high R&D costs for the combined pipeline. There is also a high degree of risk in reaching this valuation due to the higher levels of uncertainty about Cell Therapeutics' market potential. Their lead product is in Phase III, which has an average 60% probability of success[9], and the revenue projections are based on this product succeeding. On March 7, 2005, the company released news that indicated that this Phase III product missed its primary endpoint of improved efficacy over current standards of care (Berkrot, 2005), and therefore the revenue, income, and growth projections will need to be revised downward.

4.5.2.3.2 Product and Pipeline Compatibility

Cell Therapeutics has a drug delivery technology that makes cancer drugs more water-soluble by linking a polymer to a chemotherapy agent. The company has one commercial product and four clinical development products, as well as a number of preclinical research and development stage products to treat various forms of cancer. There are two development products

[9] See section 2.1.2

in Phase III, and two in Phase II, with the earliest NDA submission for lung cancer with XYOTAX targeted by the end of 2005[10]. Appendix 19 summarizes the commercial and clinical pipeline products. Following the March 7th, 2005 news release on the Phase III results, there is uncertainty about whether the company will proceed with submitting an NDA for marketing approval of XYOTAX (Berkrot, 2005).

4.5.2.4 Barrier Therapeutics Inc.

Barrier Therapeutics Inc. (NASDAQ: BTRX) is specialty pharmaceutical company focusing on discovery, development, and commercialization of dermatology products. The company was spun out of the Johnson & Johnson family of companies in 2001 to focus on dermatology, and went public in mid-2004 (Barrier Therapeutics, Inc., 2005)[11]. The company is headquartered in Princeton, New Jersey, with subsidiaries in Geel, Belgium and Ontario, Canada. Barrier Therapeutics has a strong management team with extensive pharmaceutical industry experience. The founder of the company and its current Chairman and CEO Dr. Geet Cauwenbergh, 49, was formerly a Vice President with Johnson & Johnson. There is currently no president at Barrier Therapeutics.

4.5.2.4.1 Financial Feasibility

With a market capitalization of $402 million and a 28% deal premium, it would cost QLT $515 million to purchase Barrier Therapeutics. QLT can offer 50% of the purchase price in cash, which is $257 million. The remainder of the purchase would require the issuance of 19.1 million common shares at $13.46 per share (based on QLT's current share price) for a total of $257.3 million in stock. The current market capitalization of Barrier Therapeutics makes it a financially feasible acquisition target.

The estimated financials for Barrier Therapeutics and the combined companies to 2010 are summarized in Appendix 20. Using the assumptions listed in Appendix 16, the combined company (QLT and Barrier Therapeutics) net income in 2010 is estimated at $130 million with an annualized average 5 year growth rate of 45% and EPS of $1.11 (117,114,413 shares outstanding). The acquisition would dilute the value of QLT's shares by 71% in 2005, 66% in

[10] Subsequent to our analysis of the companies, which was carried out on March 3rd, 2005, Cell Therapeutics announced disappointing results for their lead Phase III product. The company's market capitalization has dropped dramatically, but we elected to proceed with our analysis based on the previous data.

[11] All Barrier Therapeutics background information was obtained from their corporate website (Barrier Therapeutics, Inc., 2005).

2006, 31% in 2007, 1% in 2008, then be accretive to value of QLT's shares by 9% and 22% in 2009 to 2010, respectively. In this deal QLT would be able to maintain near-term profitability, but the growth potential of the combined business is also limited, and will not achieve QLT's 2010 growth objectives.

4.5.2.4.2 Product and Pipeline Compatibility

Barrier Therapeutics recently acquired a cosmeceutical product for liver spots, Solage, which the company plans to market in the U.S. and Canada. There are eight candidates in clinical development, and a number in preclinical development, with one expected to advance to clinical trials in 2005. Appendix 20 summarizes the commercial product and clinical development pipeline.

4.5.2.5 Cell Genesys Inc.

Cell Genesys Inc. (NASDAQ: CEGE) is a South San Francisco based company developing biological therapies for cancer. The company has two major product platforms: cancer vaccines and oncolytic virus therapies (Cell Genesys, Inc., 2005)[12]. The company is also working on developing products from a third platform, antiangiogenesis. This company is at an earlier stage of development than any of the other companies we have evaluated, but we decided that it would be an interesting company to analyze because of its cancer vaccine and gene therapy platforms, which put the company in the forefront of some of the emerging trends in biotechnology discussed in section 2.3.4 and could potential fill QLT's strategic innovation gap. We chose this company out of the potential cancer vaccine companies because of its lead product candidate in prostate cancer, robust pipeline, and anti-angiogenesis platform, which could provide further oncology candidates as well as potential wet AMD candidates. The company's senior management includes Dr. Stephen Sherwin, age 55, Chairman and CEO since 1990, prior to which he was Vice President of Clinical Research at Genentech, and President and Chief Operating Officer, Dr. Joseph Vallner, age 57.

4.5.2.5.1 Financial Feasibility

With a market capitalization of $280 million and a 28% deal premium, it would cost QLT $358 million to purchase Cell Genesys, making this the least expensive deal considered. QLT can offer 50% of the purchase price in cash, which is $179 million and still have a cash balance of

[12] All Cell Genesys background information was obtained from their corporate website (Cell Genesys, 2005).

approximately $200 million remaining for other business development opportunities. The remainder of the purchase would require the issuance of 13.3 million common shares at $13.46 per share (based on QLT's current share price) for a total of $179.2 million in stock.

The estimated financials for Cell Genesys to 2010 are summarized in Appendix 21. Using the assumptions listed in Appendix 16, the combined company (QLT and Cell Genesys) net income in 2010 is estimated at $149.8 million with an annualized average 5 year growth rate of -53.6% and EPS of $1.35 (111,313,522 shares outstanding). The acquisition would dilute the value of QLT's shares by 96% in 2005, 111% in 2006, 106% in 2007, 85% in 2008, 19% in 2009 then be accretive to value of QLT's shares by 48% in 2010. The growth rate of the combined company is relatively high, but this is in large part because QLT would face net losses for several years, making the near-term profitability of a deal very unattractive. The combined income by 2010 is also short of the 2010 target of $220 million.

4.5.2.5.2 Product and Pipeline Compatibility

Cell Genesys currently has six products in its clinical development pipeline, and no commercial products. The GVAX cancer vaccine is comprised of cancer cell lines that are genetically modified to produce a factor that stimulates the patient's immune response. Its lead product is a cancer vaccine for prostate cancer, in Phase III clinical trials. Some of the cancer vaccines are patient-specific, moving closer to the personalized medicine model discussed as an emerging trend in the biotechnology industry in section 2.3.4. The long clinical study timelines for cancer products makes any commercial launch unlikely prior to 2008. Appendix 21 summarizes the development pipeline.

4.5.3 Deal Candidate Summary

Based on each of the candidate company's therapeutic focus, pipeline, and financial situation, we assigned a score against their degree of strategic and corporate fit in filling QLT's growth and capability gaps. Each candidate is given a score out of 4 for therapeutic area fit, pipeline gap, sales gap, financial gap in terms of near-term and long-term profitability, new drug delivery platform/innovation, new markets, and management fit.

In Table 8, we summarize these scores and rank the five deal candidates according to their overall score. Therapeutic area fit is an indication of the synergies between the deal candidate's and QLT's therapeutic areas, and a higher score is assigned to companies with greater alignment in their therapeutic focus. The score for pipeline gap is based on how well each

candidate fills the late-stage gaps in QLT's development program. Higher scores are given to companies with a higher number of products in late stage development for complementary markets to QLT. The sales gap score is determined by the deal candidate's ability to provide a commercial sales force in one or more of QLT's therapeutic areas. The financial gap is comprised of two components: near-term and long-term profitability. Near-term profitability is important so that QLT's share value is not overly diluted by a deal, and long-term profitability is based on whether a deal can provide the growth rates and net income to achieve QLT's 2010 targets. Higher scores are given to companies with higher profitability. The score for new drug delivery is determined by the deal candidate's ability to provide access to new and innovative drug delivery platforms that are complementary to QLT's drug delivery systems. Higher scores are given to companies with more innovative platforms or multiple platforms. The new markets dimension is determined by the potential for QLT to enter new markets through the acquisition. Higher scores are given to candidates with commercial and/or products across a range of new markets for QLT. Management fit is the likelihood that an M&A deal can be negotiated that will be acceptable to both QLT's senior management and the deal candidate's management. Higher scores are given to companies whose CEO may be more open to being acquired by QLT or merging with QLT as the lead organization, based on the candidate CEO's age, length of time with the company, and status as a founder. We consider founding CEO's to be less likely to be receptive to being acquired. The scores from all dimensions are totalled for each deal, and provide a starting point for the recommendations in chapter 5.

Table 8 Deal Candidate Summary

	Connetics Corporation	Ligand Pharma.	Cell Therapeutics	Barrier Therapeutics	Cell Genesys
Therapeutic Area	2	2	2	1	2
Pipeline Gap	2	3	3	3	2
Sales Gap	3	4	2	2	0
Near-term Profits	3	2	0	1	0
Long-term Profits	2	4	4	2	2
New Drug Delivery/Innovation	2	1	3	1	4
New Markets	2	3	4	3	4

	Connetics Corporation	Ligand Pharma.	Cell Therapeutics	Barrier Therapeutics	Cell Genesys
Management Fit	1	2	1	2	1
TOTAL (out of 32)	**17**	**21**	**19**	**15**	**15**

In addition to these scores, any M&A decision needs to consider other organizational factors such as corporate values and culture fit, as well as implications for QLT's stakeholders. Another factor is whether the company's headquarters are currently in a major U.S. biotechnology cluster and provide the opportunity for QLT to establish a strong presence in one of these areas. The major stakeholders that need to be considered in an M&A are the major investors, shareholders and the employees.

QLT's senior management will need to demonstrate to its shareholders and its employees the strong value in combining its business, especially in light of the generally negative stock performance of companies carrying out an acquisition, and the difficulty that many employees have with the changes following an M&A. All these companies are located in the U.S., and there will be additional questions for their shareholders and senior management whether a headquarters in Canada will be compatible with their organizational goals. In the following chapter, we recommend whether to proceed with one of these potential acquisitions, and develop a strategy for successfully executing the deal, taking into account the implications for the major stakeholders and the challenges with maintaining and building value following an M&A.

5 RECOMMENDATIONS AND ACTION PLAN

QLT's objective to become a top ten biotechnology company by 2010 is ambitious but achievable if QLT is able to execute its growth strategies. Our analysis of QLT's industry and internal environment has led us to recommend that QLT expand its product pipeline and revenue potential through product and business acquisition strategies to meet its growth objectives for 2010. In this chapter, we prioritize the potential merger and acquisition deals evaluated in the previous chapter, and outline a strategy for realizing the recommended deal. We then provide an action plan and financing strategy for all of the recommended next steps for QLT to achieve its growth objectives. We also discuss the effect of our assumptions on our analysis and outline alternatives to consider should these assumptions change. Finally, we recommend areas for further research and analysis to build upon the recommendations for growth provided in this paper.

5.1 Prioritization of Deals

The choice of a business development deal must be made to maximize shareholder value and corporate growth in the long term, without overly comprising near term value and earnings. Our analysis of merger and acquisition (M&A) targets carried out in section 4.5 leads to the following ranking of the deal candidates: Ligand Pharmaceuticals first, followed by Cell Therapeutics, then Connetics Corporation, and Barrier Therapeutics and Cell Genesys tied for last place. We recommend that QLT prioritize Ligand Pharmaceuticals as an acquisition target for reasons outlined in more detail below. Cell Therapeutics is a strong business development candidate, but we feel that the loss of near term profitability that would occur from this acquisition would not be acceptable to QLT's shareholders. The failure of its Phase III product to meet its primary endpoint for efficacy also casts doubt on its entire platform, which is based on the premise that increased solubility will improve cancer drug efficacy while reducing its toxicity.

Ligand Pharmaceuticals offers an M&A target that has less compelling upside growth potential than Cell Therapeutics, but offers a less risky approach to growing QLT. A deal with Ligand would allow QLT to potentially meet its 2010 growth objectives. Ligand Pharmaceuticals' primary strengths relative to QLT's strategic requirements are its dermatology and oncology sales

forces, and a late-stage clinical development pipeline. The company also has a commercial product in pain with strong revenue growth potential, and although it is outside of QLT's therapeutic focus, this product could fuel earnings growth and cash flow to pay for development of other pipeline products. Another major strength is the company's near term profitability, which would sustain and enhance QLT's near and longer term earnings. Even if the late stage development products in Ligand's pipeline were to fail to gain marketing approval, the combined company would have sufficient resources through its current revenue streams to sustain substantial new product development activities. A further advantage of a deal with Ligand would be the opportunity for QLT to have an office and significant operations in San Diego, which is a top U.S. biotechnology cluster.

Potential weaknesses of a deal with Ligand include the company's reliance on two primary products for revenues in the near term: its pain product and its Phase III cancer product, which may not provide adequate diversification for QLT's revenue stream to buffer any unforeseen risks with its revenue drivers. Other weaknesses include Ligand's focus on small molecule development, which does not provide any enhancement of QLT's current core capabilities, and its specialty pharmaceutical status, which leads to a lower valuation on average. The current valuation of both companies also means that an acquisition would leave QLT with a limited cash balance and room to manoeuvre on other potential business development deals, such as in-licensing. However, the combined profitability of the businesses should allow the company to consider future business development deals when Ligand's late stage cancer product is launched. Investigating potential competitors for Ligand's lead pipeline products was also beyond the scope of our analysis, and there is the possibility that significant competition could threaten or reduce the revenue potential of its products. Ligand has a high P/E ratio, which is positive in that it indicates general investor confidence and interest in its growth potential, and is a negative for a potential acquisition with QLT as a lead partner, because of the potential high cost of this deal.

The balance of strengths versus weaknesses leads us to recommend that QLT carry out further preliminary analysis on Ligand Pharmaceuticals to determine whether to continue to a full due diligence prior to making an offer. Because of the uncertainties with the outcome of a due diligence and also with the financial feasibility of a reasonable offer for QLT, or the acceptability of an acquisition to Ligand Pharmaceuticals, we recommend that QLT investigate Cell Therapeutics further as well.

Depending on QLT senior management's tolerance of short term loss of profitability and higher degree of risk, Cell Therapeutics could also be a reasonable choice for acquisition for a number of reasons.[13] The company has a broad pipeline in cancer with a couple of development products near commercialization, with high sales and revenue potential. Cell Therapeutics also has an established sales force for cancer and a commercial product, which does not have high revenue potential but provides the company with an excellent learning experience in marketing and sales that it can leverage for more profitable products down the road. Because of the high revenue potential and medium level of market capitalization around $600 million, a deal with Cell Therapeutics would involve the least amount of dilution of value for QLT's shareholders in the long run. Also important is Cell Therapeutics' drug delivery technology, which would complement and enhance QLT's core capability in drug delivery platforms. Another factor that makes this business combination attractive is the close proximity of the two companies, with Cell Therapeutics location in Seattle making business integration and operations easier and reducing the potential culture gap.

There are some potential drawbacks to a potential acquisition of Cell Therapeutics. The primary downside is that QLT would become unprofitable for at least one year, when combined with Cell Therapeutics high clinical development costs in 2005. Furthermore, there is some degree of risk that Cell Therapeutics' clinical pipeline products may fail to meet their desired endpoints for safety and efficacy, and not deliver its positive upside growth potential. The high cost combined with the pipeline risk means that if Cell Therapeutics were to fail in clinical development, QLT's finances would be too depleted to recover and build the needed pipeline in time to achieve its 2010 growth and valuation objectives. As a therapeutic area, cancer has many companies working on therapies and there is heavy competition for the larger markets and relatively few high potential, unmet needs. Cell Therapeutics defines itself as a cancer company, and may be unwilling to relinquish this identity. The company has a relatively young CEO who was also a company founder, increasing the likelihood that the company may wish to remain independent and in full control of its strategic direction, and thus would not accept a reasonable acquisition offer.

We do not recommend that QLT expend any effort investigating Connetics, Cell Genesys, or Barrier Therapeutics further for acquisition at this time, because of clear and

[13] This analysis was also carried out prior to Cell Therapeutics negative news on March 7th, 2005. The drop in valuation of the company after this news and the deep pipeline may still make Cell Therapeutics worth investigating.

numerous shortcomings in these companies' abilities to fill QLT's pipeline product and strategic gaps. Connetics is profitable, has an experienced dermatology sales force and drug delivery technology, but the development product pipeline is relatively weak and there is no evidence of preclinical research to build a stronger pipeline in the near term, and we do not see the potential for sufficient income to enable the acquisition of strong pipeline candidates. Cell Genesys has intriguing technology platforms and a lead product in prostate cancer, but the risk of failure is too high and the timelines to revenues are too long to fulfil QLT's 2010 growth objectives. Barrier Therapeutics also has the beginnings of a commercial sales force in dermatology, and a number of development products near commercialization, but the overall sales and revenue potential of these products is too limited to enable the revenue and income growth rates that QLT needs to become a top ten biotechnology company by 2010.

A caveat to our recommendation is that there are some weaknesses in our deal candidate evaluation methodology and framework. First, our search was limited to public companies because of our need for accessible information. Our reliance on publicly disclosed information from the Internet may also have biased our screening because may have excluded companies that had undisclosed drug delivery expertise or therapeutic focus in QLT's areas. During our initial screen, we relied on company summaries posted on the Internet, which may not have been up to date. As mentioned above, our detailed candidate evaluation did not include any market potential or competitor analysis other than disclosed by the company. QLT's senior management may also place higher value on some of the strategic factors that we used to rank the deal candidates than others, which could lead to different weighting of these factors and different conclusions.

5.2 Strategy for Realizing Deal

The strategy for successfully completing a business combination with Ligand Pharmaceuticals must meet the needs of the major stakeholders of both QLT and Ligand. Based on the stakeholder analysis in section 3.7, the major stakeholders that QLT needs to consider in an M&A scenario are the institutional investors, senior management, Board of Directors, and employees. We assume that Ligand will have the same major stakeholder concerns. In this section, we consider how to design a deal that will be feasible for QLT and attractive for Ligand, and acceptable to both sets of stakeholders. We follow with a discussion of strategies to mitigate any major stakeholder concerns.

Typical M&A issues in the biotechnology industry include key employee retention, lack of cultural fit, disconnect between due diligence team and strategic team and unclear post-

transaction planning in terms of objectives and responsibilities (Doyon, 2003). In addition, stakeholders are predominately concerned with near-term dilution and job loss at the executive level (Esposito and Ostro, 1999). Other obstacles to effective M&A deals are willingness of management, agreement on valuation, fit among scientists and the right balance of commercial products and pipeline (Malloy, 1999). For a deal to feasible, acceptable and attractive to both QLT's and Ligand's stakeholders, it must address these issues and concerns.

5.2.1 Deal Structure

In order to execute a deal with Ligand, we recommend that QLT structure an offer as a merger of equals. Ligand's commercial presence and potential make them unlikely to accept acquisition, whereas we believe the company could be open to a strategy of merging in order to build assets and growth together that could not be achieved alone. Ligand acquired Seragen in 1998 (Ligand Pharmaceuticals, 2005), and Glycomed in 1995 (Informagen, Inc., n.d.), indicating that the company is open to business combinations as a growth strategy. Some of the primary advantages of a merger between these companies would be higher economies of scale, larger combined cash balance for future business development, complementary capabilities and synergies in research, development, manufacturing, and commercialization, and reduced risk for each company from a broader overall pipeline. The combined company would have a market capitalization of at least $2 billion, increasing its profile with investors, and giving it a larger presence in the biotechnology industry, which will be advantageous for doing any business development deals down the road. In addition, with Ligand's recent achievement of profitability, QLT can offer the experience and financial expertise to manage a profitable company, both from a cash flow perspective and an investor and corporate communications perspective.

We assume that QLT will want to retain leadership over a merged company, and keep its headquarters in Vancouver. QLT should offer a slight premium to Ligand's shareholders for their loss of sole control over the leadership of the company. We recommend that this merger be carried out as a cashless transaction for its tax advantages and to preserve cash for future development opportunities. To execute the merger, a new corporation should be set up that will issue shares to each of Ligand's and QLT's current shareholders in proportion to their closing market price on the day that the deal is closed, plus the deal premium for Ligand. For example, at a valuation of $798 million for Ligand (Table 7), an 8% premium would bring its merger value up to $862 million. At a $1.1 billion valuation for QLT (Appendix 1), QLT's shareholders would receive 52% of the shares in the combined company, and Ligand's shareholders would receive 48% of the shares of a merged company valued at $1.8 billion total. This structure would result in

approximately 15% dilution initially for QLT's shareholders, and 8% accretion in value for Ligand's shareholders. We also recommend that the company select a new name for the combined entity that reflects their merged status.

5.2.2 Stakeholder Strategies

QLT and Ligand will have to develop strategies to convince their stakeholders that this merger is to both company's advantage. The post-merger valuation of $1.8 billion would put the company very close to the top 20 biotechnology companies immediately, and position the company for growth over the next five years to achieve a top 10 ranking among biotechnology companies. This higher valuation will increase the profile of the merged company in the industry, and strengthen its ability to raise capital and become a partner of choice for smaller biotechnology companies. The combined commercial product lines will be much better diversified, reducing risks to current revenues, and a robust development pipeline in place to reduce the risk to future cash flows.

QLT can use the following rationale to promote this deal to its shareholders:

- Addition of commercial sales force
- Diversification of revenues and pipeline
- Increased growth potential
- Improved economies of scale
- Combined strength and valuation of the company increases its profile and ability to negotiate stronger deals in the future.

Ligand Pharmaceuticals can use the following rationale to promote this deal to its shareholders:

- Diversification of revenues and pipeline
- Increased profitability
- Addition of financial expertise in managing profitability
- Stronger balance sheet: reduced debt ratio and improved cash balance
- Increased growth potential
- Improved economies of scale
- Combined strength and valuation of the company increases its profile and ability to negotiate stronger deals in the future.

External stakeholders should be managed through a well informed corporate communications team that understands the impact of the merger on these stakeholders. Consistent and clear communication is important given the wide range of stakeholders and the reliance on these external parties for continued growth and success. Financial analysts have a strong influence on the perceived value of the company, and are key to gaining acceptance of the merger from investors and the financial community. An investor package should be developed that explains the goals and objectives of the merger, and clearly demonstrates the increased value of combining businesses.

An internal change management team should be formed to manage and address internal stakeholder concerns for the planned merger. Senior management must give this team the responsibility for ensuring that all internal stakeholders receive clear and timely information on the merger process. Human resource issues should also be addressed by the change management team, and key employees should be managed on an individual basis to ensure key employee retention. To build cultural fit between QLT and Ligand employees and management, the change management team should conduct workshops on the change management process to facilitate the transition and educate these stakeholders on the goals and objectives of the merger. Workshops provide a dynamic environment to discuss concerns openly and honestly, and can facilitate employee and management buy-in. For the scientific groups, cross-training is an excellent tool to allow learning between the groups as it increases individual skills and capabilities, and ensures a smooth transition of research and development initiatives post-merger.

5.2.3 Risk Mitigation

To mitigate risks and challenges inherent in M&As, a number of measures can be taken to improve the success of the merger. First and foremost, an amicable relationship between the CEO's of the two companies will be essential to allow any discussions to go forward. The deal terms and post-merger organizational structure and management will have to be very carefully negotiated and made explicit. An additional cash payment may need to be offered to Ligand's current President and CEO to step down from his position. As compensation for this loss of senior management control, a Ligand representative should be appointed as Chair of the combined Board of Directors.

Senior management must also prioritize the relationship between the due diligence and corporate strategy teams. It is critical that both teams understand the key drivers and strategic rationale for the merger. These teams have the responsibility for determining an acceptable

valuation for both parties in the merger, and ensuring that the commercial product and pipeline portfolios have adequate resources post-merger. The valuation of the combined company will be based on the performance of the combined commercial products and the perceived value of the combined pipeline. Therefore, the sales and marketing efforts should maximize the value of marketed products, while the internal research and development efforts should maximize the value of the pipeline by focusing on innovative, high potential products to position the combined company for sustained growth.

There is also a risk that competing companies could make a more attractive M&A offer to Ligand Pharmaceuticals. The type of companies that could pose a threat to QLT completing a deal would be a higher market capitalization biotechnology company that would offer a much higher short term return to Ligand's shareholders because of their ability to offer a large cash premium and possibly higher growth potential in the long run. More well-known companies with a stronger industry reputation than QLT could also generate competition for an M&A with Ligand as they would offer a high profile deal that would generate more favourable publicity among the investment community.

QLT can mitigate the risk of losing a bidding process for Ligand with a larger company by emphasizing the advantages of a merger structure that would give Ligand management and shareholders equal control over the future direction. QLT should also emphasize the unique synergies and combined strengths that a merger could create, particularly in dermatology and cancer, and the advantages of the company's experience in managing and sustaining profitability. By merging with QLT, Ligand would also gain access to many strategic partnerships that QLT has built with their commercial partners, namely Novartis, Sanofi-Aventis, Sandoz, Astellas and Pfizer.

5.3 Overview of Next Steps

Our recommended next steps for QLT to execute its growth strategy are as follows:

- Investigate Ligand Pharmaceuticals further to determine the feasibility of our recommended merger and make a decision on whether to carry out full due diligence.

- Obtain marketing approval for Aczone™ in Acne in Europe and build a dermatology sales force in Europe to market this product.

- Investigate acquiring the marketing rights to high market potential, innovative late-stage clinical development candidates in dermatology, prostate cancer, or ophthalmology, especially the AMD market, through partnering or in-licensing. QLT should look for two to three moderate to high market potential candidates.

- If rights to market a late stage candidate are acquired in prostate cancer or dermatology, renegotiate the marketing rights for Aczone™ and Eligard® to re-acquire full promotional rights in house, and build sales force.

- Investigate preclinical stage targeted drug delivery platforms or combination products for in-licensing to build on drug delivery and combination product core capabilities, particularly in emerging areas such as gene-based therapies or personalized medicine.

For the partnering and in-licensing strategies, it is critical that QLT choose a large market potential candidate to justify the high cost of acquiring the marketing rights to a late stage product. There will likely be heavy competition from other biotechnology companies for partnering or in-licensing products with large market potential. In order to succeed in closing a deal versus companies with proven sales track records, QLT may need to be willing to pay a slight premium for products with higher than average risk. QLT should negotiate deal terms that mitigate this risk by deferring payments to future milestones and select candidates that can provide very strong returns to compensate for the increased risk. However, QLT should be careful not to offer overly high royalty payments that would reduce the future value of the product to QLT. Doing several of these types of deals will create a diverse development portfolio that will also mitigate the risk of failure of any one product.

Because of the uncertainty and potential delays in completing a merger, we recommend that QLT proceed with executing the partnering and in-licensing strategies immediately. The preliminary M&A evaluation can be carried out concurrently, and with the deal structure that we are recommending, any payment for a partner or in-licensing deal should not affect the ability to close a merger of equals. However, once an M&A decision is finalized, QLT should put further in-licensing or partnering investigations on hold until integration is completed and the combined company agrees on the best new strategies for growth.

5.4 Financing Strategy

The high cost of drug development requires that QLT focus on acquiring only the most promising product candidates and minimize its exposure to risk of failure. This can be accomplished by staging payments to partner companies based on achievement of specific development milestones. To acquire the marketing rights to a late stage drug candidate (PII/PIII), QLT will need to offer a partner an upfront payment as well as milestones payments that are contingent on meeting predetermined clinical development targets. In 2004, the average deal terms for licensing late stage technology were $18 million upfront and $75 million in milestone payments (McCully and Van Brunt, 2005). QLT will also need to offer royalty payments as a percentage of net sales that apply when the product is commercialized, typically in the 8-40% range for a late stage development product (McCully, 2005). QLT should be prepared to offer slightly higher upfront, milestone, and royalty payments than this average, up to a 25% premium, to persuade companies to accept the company's lack of sales experience.

To in-license an early stage drug delivery technology, QLT will need to offer an upfront payment as well as milestone payments that are contingent on meeting predetermined development targets throughout the drug development process. In 2004, the average deal terms for licensing early stage technology (i.e. discovery or lead stage) were $10 million upfront and $98 million in milestone payments (McCully and Van Brunt, 2005), making these deals slightly less expensive than late stage deals upfront, but leaving a larger commitment in milestone payments. Given the increasing trend in early stage deal terms, QLT should plan on providing $13 million upfront and $110 million in milestone payments to in-license an early stage drug delivery technology in 2005. QLT will also need to offer royalty payments that apply when the product is commercialized, typically much lower for early stage deals, in the 10% range (McCully, 2005). QLT would be responsible for developing the drug delivery technology in order to launch new drug development programs in the company's current therapeutic areas. Given QLT's current earnings level, resources, and preclinical programs, the company should only commit to one deal at this stage, and wait for a promising clinical candidate to appear before committing to any further deals.

For both the late stage and early stage deals, QLT can use its cash balance to fund the upfront payment, and cash flow from revenues to provide funding for the ongoing milestone payments for at least one product. If the company is able to in-license three late-stage products as we recommend, however, it is likely that using cash flow alone to pay for developmental

milestones might result in a significant drop in earnings. The company will have to carefully consider the consequences of decreased earnings in terms of investor confidence and financial analyst sentiment. We believe that some decrease in earnings will be acceptable to investors and analysts if it is justified by the development of a very promising candidate, and is preferable to using the cash balance to make milestone payments. QLT will need to use some of its cash balance to cover the upfront payments for an in-licensing or partnering deal, and then should endeavour to use cash flow for milestone payments while minimizing the decrease in earnings.

QLT has several other strategies available for increasing its working capital while preserving cash to carry out future business development deals. QLT should aim to reduce operating costs wherever possible in order maximize earnings and available cash flow. Reduced operating costs also affect the bottom line, firm performance and growth. Another important strategy for minimizing costs is to kill bad projects early and avoid costly development failures that can rapidly deplete resources. By implementing managerial systems that encourage the termination of ailing projects, management can minimize development expenses and ensure that employee incentives are aligned with the goal of minimizing costs. Large capital expenditures should also be minimized wherever possible to reserve working capital for operations and future business development deals. The company can also consider offering equity in lieu of royalty payments, particularly if it negotiates strategic partnership deals rather than in-licensing down the road, but needs to consider the trade-off between potential dilution and cash flow.

5.5 Caveats and Assumptions

For the purpose of this paper, we assumed that QLT's goal is to remain independent. However, another option to maximize shareholder value could involve divesting ownership through being acquired. If QLT were to be acquired by another company instead of remaining independent, shareholders could receive immediate returns and faster gains on share value. However, the loss of independence and control can make this route a challenging one for increasing QLT's shareholder value. As QLT's market capitalization to book value drops, QLT's senior management must be aware that the company will become a more appealing acquisition target, and have strategies in mind to deal with this possibility. Rather than automatically rejecting any merger or acquisition offers from larger companies, QLT's senior management must consider the best options for its major stakeholders, especially its shareholders and employees.

We also did not challenge QLT's underlying objective of becoming a top ten biotechnology company by 2010, but senior management may want to revisit this goal if the appropriate M&A targets are not available in the next couple of years. The growth targets are very aggressive, and could lead to destabilization of the company if not very carefully managed. QLT should consider whether this extent of growth is actually in the best interest of its shareholders, and whether it is realistic from an organizational change perspective.

Our analysis also assumed that the top ten companies would grow at a constant rate and that market valuation multiples would also remain constant. In reality, the biotechnology industry and its companies are highly dynamic. Companies currently below the top ten ranking were not evaluated for their growth potential, and could grow at a faster rate than QLT or the current top ten companies and replace them. Even the changes in fortune to one key product can have an enormous impact on a company. For example, Elan recently fell out of the top ten rank and suffered a more than 70 % drop in market capitalization on February 28, 2005 following the withdrawal of a multiple sclerosis drug with large potential sales that the company was marketing along with Biogen Idec, which fell nearly 43% (Jewell, 2005). While this situation worked against Elan, QLT should keep in mind that investor perception and sentiment can also work strongly in favour of a company that has a very promising product in its pipeline. This example also confirms the importance of a diversified pipeline, which protected Biogen Idec from suffering such a large decrease in market capitalization.

5.6 Follow-up Research and Analysis

As part of an analysis of the feasibility of a merger with Ligand Pharmaceuticals, QLT should research the competitive situation for Ligand's target markets. For Ligand's commercial products, QLT should conduct further analysis on new competitors to determine if there are any imminent threats to Ligand's existing revenue streams, and calculate the period of market exclusivity to determine when generics are likely to come on the market due to patent expiration. For Ligand's late stage cancer product and other lead development candidates, QLT should identify potential competitors, and determine the degree of unmet need and market potential. On a corporate level, further in-depth research is required into Ligand's operating history and public image to ensure there is no negative publicity that could adversely affect QLT's reputation. QLT should also research the market to determine if there are competing interests for an acquisition of Ligand among other biotechnology and pharmaceutical companies.

As a contingency to the proposed merger with Ligand, QLT should conduct further in-depth research into Cell Therapeutics and other M&A candidates to determine the feasibility of doing a different deal. M&As are a long and complex process, and there is no guarantee that the merger with Ligand will complete even after months of due diligence and strategic planning. In addition, QLT should expand the search for appropriate deal candidates to private companies using market research and other competitive intelligence information. This may uncover additional companies that have complementary core competencies, robust pipeline, high market potential products and commercial sales force in one of QLT's therapeutic areas to help QLT achieve its growth targets.

QLT should also conduct further research on other ways of increasing valuation, to achieve its corporate objective of becoming one of the top ten biotechnology companies. For example, lowering operating costs to retain a higher percentage of earnings can also potentially increase valuation. This is a low risk method of increasing value, and provides QLT with an additional opportunity to build value from within the organization. QLT should also conduct follow-up research on alternative growth strategies discussed above, such as in-licensing and partnering. Growth through mergers may not be the optimal way to build shareholder value because of the difficulty of successfully integrating companies post-merger, and other options may provide less challenging ways to build value.

Further analysis of QLT's internal values and management processes will also provide important insight into the company's ability to implement the strategies for growth and provide the basis for recommendations on how to best manage the accompanying changes. In particular, evaluation of how the proposed growth strategies fit within the context of QLT's history and culture will be critical to managing human resources impacts and successful implementation.

Addressing the company's infrastructure, operational designs and organizational structure were also beyond the scope of this analysis, and these factors will have to be carefully considered and managed to support the growth strategies outlined in this analysis. We recommend that QLT continue to consider their necessary business process and infrastructure improvements to successfully manage growth, in-license new products and technologies, and integrate acquired companies. All business processes and organizational structures should be designed to be scalable for further growth, and must also consider human resources dimensions such as fit to QLT's culture and values.

5.7 Conclusions

QLT has had a strong record of commercial success and profitability for a company of its size. If QLT can deliver on its 2010 growth objectives by completing a merger with a strong company, diversifying its commercial products, and growing its pipeline, the company will be able to provide an excellent return to its shareholders, while improving the quality of life for its growing numbers of patients. The key to continued growth, profitability and maintenance of a competitive advantage in the biotechnology industry is to be more efficient than competitors, by aiming to be on the high end of clinical success rates, on the rapid end of development timelines, and by finding significant unmet medical needs that can be solved with innovative new therapies that are hard for competitors to replicate. As the industry matures and competition for business development deals to acquire new technology becomes more intense, QLT must build a high profile and reputation in the industry that will distinguish it from other competitors for the best deals. QLT will also need to have a relatively high tolerance of risk in selecting potential business development opportunities to compensate for its relative lack of experience.

QLT can build a strong reputation through consolidating its core capabilities in innovative drug delivery platforms and combination products and by adding a commercial infrastructure. Full commercial capability will be critical to QLT's growth strategy through acquisition of rights to new products, whether through corporate merger and acquisition, partnering, or in-licensing. QLT has very aggressive growth targets, and in a high growth environment, the company will need to effectively manage rapid growth in order to increase and sustain shareholder value over the long run. QLT has thus far managed its growth effectively, and can continue to work on implementing new strategies to sustain growth while maintaining its core value of developing innovative treatments for high unmet medical needs.

APPENDICES

Appendix 1: Largest Market Capitalization Biotechnology Companies Worldwide

(Current Ranking; NASDAQ Biotechnology Index; in US$)

Company	Market Cap (B)	Revenue (B)	Earnings (B)	Net margin (%)	P/E[14]	PEG Ratio	Earnings Growth %(YOY)
Amgen, Inc.	77.2	10.6	2.36	4.5	34	1.14	30
Genentech, Inc.	49.8	4.6	0.79	5.9	65	1.76	37
Biogen Idec, Inc.	20.8	1.9	-0.99	-1.9	N/A	2.13	N/A
Gilead Sciences, Inc.	14.1	1.3	0.45	2.9	33	1.26	26
Genzyme Corporation	13.3	2.1	0.33	6.4	41	1.97	21
Elan Corporation, plc (ADR)	10.1	0.5	-0.37	-1.4	N/A	N/A	N/A
Serono S.A. (ADR)	9.2	2.3	0.52	4.5	19	1.24	15
Chiron Corporation	6.2	1.7	0.06	28.8	106	1.51	70
MedImmune, Inc.	5.8	1.1	0.02	49.1	279	4.66	60
Celgene, Inc.	4.7	0.4	0.06	6.4	108	1.28	N/A
Average	**24.9**	**2.9**	**0.65**	**17**	**58**	**2**	**37**
QLT Inc.	1.1	0.2	0.05	3.2	21	0.75	230

Source: Yahoo! Finance (2005, January 29)

[14] Average P/E ratio excludes outlier MedImmune and unprofitable companies Biogen Idec and Elan

Appendix 2: Summary Features of Top Ten Biotechnology Companies

Company: Headquarters Employees	Positioning Statement	Commercial Products; Clinical Development Pipeline (#)
Amgen, Inc. HQ: Los Angeles area Employees: >14,000	At Amgen, we're in the business of helping patients live longer and lead better lives through innovative research and therapeutics. Our success comes from one simple fact - we are committed to being a science-based, patient-driven company. This commitment guides all of our business decisions and the way we operate, as we continue our search for breakthrough treatments for grievous illness. *Source: (Amgen, Inc., 2005)*	Products: 8 Pipeline: 18
Genentech, Inc. HQ: San Francisco area Employees: >7600	Genentech, the founder of the biotechnology industry, is a company with a quarter-century track record of delivering on the promise of biotechnology. Today, Genentech is among the world's leading biotech companies, with multiple protein-based products on the market for serious or life-threatening medical conditions and over 30 projects in the pipeline. With its strength in all areas of the drug development process — from research and development to manufacturing and commercialization — Genentech continues to transform the possibilities of biotechnology into improved realities for patients. *Source: (Genentech, Inc., 2005)*	Products: 13 Pipeline: 15 (Phase II/III+ only)
Biogen Idec, Inc. HQ: Boston area Employees: >3700	Biogen Idec intends to continue its growth through discovery, development and commercialization of its own innovative products and through strategic alliances as the partner-of-choice for biologics development, manufacturing and marketing. Biogen Idec is dedicated to pursuing the creativity of science. The company's products and development programs address a variety of key medical needs in the areas of oncology, neurology, dermatology and rheumatology. *Source: (Biogen Idec, Inc., 2005)*	Products: 4 Pipeline: 17
Gilead Sciences, Inc. HQ: San Francisco area Employees: >1600	Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. *Source: (Gilead Sciences, 2005)*	Products: 7 Pipeline: 0

Company: Headquarters Employees	Positioning Statement	Commercial Products; Clinical Development Pipeline (#)
Genzyme Corporation HQ: Boston area Employees: >5600	With many established products and services helping patients in more than 80 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences to address a range of unmet medical needs. The company's products and services are focused on rare inherited disorders, kidney disease, orthopaedics, transplant and immune disease, cancer, and diagnostic testing. *Source: (Genzyme Corporation, 2005)*	Products:11 Pipeline: 21
Elan Corporation, plc (ADR) HQ: Dublin, Ireland Employees: >2100	Elan Corporation, plc is a neuroscience-based biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. *Source: (Elan Corporation, plc, 2005)*	Products: 2 Pipeline: 6
Serono S.A. (ADR) HQ: Geneva, Switzerland Employees: >4500	Serono is a global biotechnology leader with over 4,900 employees and worldwide revenues of USD 2.46 billion and a net income of USD 494 million in the year 2004. We have eight biotechnology products on the market and a strong pipeline based on both proteins and small molecules. *Source:*(Serono S.A., *2005)*	Products: 10 Pipeline: 17
Chiron Corporation HQ: San Francisco area Employees: >5300	No biotech company has had a greater impact on human health worldwide than Chiron. As a multi-dimensional company with businesses in biopharmaceuticals, vaccines and blood testing, Chiron has been at the forefront of improving lives around the globe. By developing new products, exploring new indications for existing products and expanding our market reach, Chiron will continue to bring improvement to health around the globe. *Source: (Chiron Corporation, 2005).*	Products: 5 Pipeline: 6

Company: Headquarters Employees	Positioning Statement	Commercial Products; Clinical Development Pipeline (#)
MedImmune, Inc. HQ: Washington, D.C. Area Employees: >1900	MedImmune strives to provide better medicines to patients, new medical options for physicians, rewarding careers to employees, and increased value to shareholders. Dedicated to advancing science and medicine to help people live better lives, the company is focused on the areas of infectious diseases, cancer and inflammatory diseases. The company has four marketed products and an advancing pipeline of promising candidates, all designed to treat or prevent a number of debilitating or life-threatening diseases. *Source: (MedImmune, Inc., 2005)*	Products: 4 Pipeline: 12
Celgene, Inc. HQ: New Jersey/New York area Employees: >650	Celgene is a pharmaceutical company with a major focus on the discovery, development and commercialization of small molecules for cancer and immunological diseases. Celgene's medical research and development team is working to extend the boundaries in the areas of small molecule immunotherapeutic and biocatalytic chiral chemistry by developing both new pharmaceuticals and chirally pure versions of existing drugs. *Source: (Celgene, Inc., 2005).*	Products: 3 Pipeline: 18

Source: Company headquarters and employee from Yahoo! Finance (2005, March 15), company product and pipeline numbers from company Internet websites (see source under Positioning Statement).

Appendix 3: Comparable Specialty Pharmaceutical Companies

(Current Ranking; NASDAQ Biotechnology Index; in US$)

Company	Market Cap	Revenue (B)	Earnings (B)	Revenue/ Earnings	P/E	PEG Ratio	Earnings Growth %(YOY)
Forest Laboratories, Inc.	15.12B	3.11	0.897	3.47	17.27	0.94	18.38
Allergan, Inc.	10.02B	1.97	0.174	11.32	58.97	1.49	39.58
Sepracor Inc.	5.95B	0.381	-0.296	-1.29	NA	N/A	N/A
Shire Pharmaceuticals	5.65B	1.33	0.333	3.99	17.70	1.12	15.81
Warner Chilcott plc (ADR)	3.02B	0.464	0.118	3.93	25.48	N/A	N/A
Biovail Corporation (USA)	2.55B	0.808	0.019	42.53	133.58	0.71	188.15
King Pharmaceuticals	2.54B	1.3	0.334	3.89	807.69	2.02	399.85
Connetics Corporation	864.30M	0.144	0.025	5.76	47.22	0.71	66.50
Ligand Pharmaceuticals	770.37M	0.163	-0.047	-3.47	NA	N/A	N/A
Bradley Pharmaceuticals	218.23M	0.1	0.02	5.00	11.30	0.73	15.48

Source: Yahoo! Finance (2005, January 29)

Appendix 4: QLT Selected Annual Financial Data

($US millions unless otherwise noted)

	2004[15]	2003	2002	2001	2000
Income Statement					
Total Revenues	186	146.8	110.5	83.4	32.4
Revenue growth rate (% YOY)	27%	33%	32%	157%	-
Net Income	56.8	44.8	13.6	71.5	4.4
Net Profit Margin	31%	31%	12%	86%	14%
Earnings per share (basic, $US)	0.54	0.65	0.20	1.05	0.07
Earnings growth rate (% YOY)	27%	229%	-81%	1525%	
Balance Sheet					
Cash, and equivalents	380	495.4	207.9	162.8	165.4
Total assets	N/A	634.7	345.8	317.9	260.0
Long-term debt	N/A	172.5	-	-	8.7
Shareholders' Equity	N/A	433.4	313.5	292.7	236.0

Source: QLT Inc. (2005, February 23) for 2004 and QLT Inc. (2004, April 28) for all other financials.

[15] 2004 data are from non-GAAP adjusted pro forma statements.

Appendix 5: QLT's Development Pipeline and Commercial Products

	Preclinical	Phase I	Phase II	Phase III	NDA	Market
Ocular	Atrigel® Intra-Ocular Delivery			Visudyne® MC, Occult		Visudyne® PC, MC, Occult
Oncology/Urology	ILK MICRas	Atrigel® - Octreotide Carcinoid Syndrome	Lemuteporfin BPH		Eligard® 6 months	Eligard® 1,3,4 months
Dermatology	Lemuteporfin Acne Topical Anti-psoriatic		Aczone Rosacea		Aczone™ Acne	Sandoz Partnership
Opportunistic	PYY Risperidone GHRP-1		Bone regeneration			

Source: QLT Inc. (2005, January 13)

Appendix 6: Visudyne® Estimated Sales and Revenues 2005-2015

Product: Visudyne®
Indication: wet AMD

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Assumptions:											
wet AMD Market Size ($M)[1]	1000	1050	1103	1158	1216	1276	1340	1407	1477	1551	1629
Market Growth Rate[2]	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
Target % of Market[3]	50%	45%	40%	35%	30%	25%	20%	15%	5%	3%	2%
Target market growth rate		-10%	-11%	-13%	-14%	-17%	-20%	-25%	-67%	-40%	-33%
Expense % of Sales[4]	36%	36%	36%	36%	36%	36%	36%	36%	36%	36%	36%
Royalties[5]	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Financials: All US$ millions											
Total Sales	500	473	441	405	365	319	268	211	78	49	34
Expense	180	170	159	146	131	115	96	76	28	18	12
Net Sales	320	303	282	259	234	204	172	135	50	31	22
Less royalties	160	151	141	130	117	102	86	68	25	16	11
Revenues	160	151	141	130	117	102	86	68	22	14	10

Notes:

1 Cohen Independent Research Group, Inc. (2004)
2 Table 3, Bhatti (2004)
3 Based on $448M Visudyne® 2004 sales (QLT Inc., 2005, January 20) and competitor (Macugen®) coming on market in Q2 2005; patent expiry in 2012
4 QLT Inc. (2004, November)
5 Based on 50:50 partnership with Novartis (QLT Inc., 2005, February 17)

Appendix 7: Eligard® Estimated Sales and Revenues 2005-2015

Product: Eligard®
Indication: Prostate Cancer

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015*
Assumptions:												
	Market Size ($M)[1]	1500	1538	1576	1615	1656	1697	1740	1783	1828	1873	1920
	Market Growth Rate (Avg)[2]	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
	Target % of Market[3]	8.0%	10.0%	10.0%	8.0%	7.0%	6.0%	5.5%	5.5%	5.5%	5.0%	4.0%
	Target market growth rate		25%		-20%	-13%	-14%	-8%			-9%	-20%
	Expense % of Sales[4]	34%	34%	34%	34%	34%	34%	34%	34%	34%	34%	34%
	Royalties[5]	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Financials:	All US$ millions											
	Total Sales	120	154	158	129	116	102	96	98	101	94	77
	Expense	41	52	54	44	39	35	33	33	34	32	26
	Net Sales	79	101	104	85	76	67	63	65	66	62	51
	Less royalties	40	51	52	43	38	34	32	32	33	31	25
	Revenues	40	51	52	43	38	34	32	32	33	31	25

Notes:

* Eligard® patent expires in 2018 (Atrix Laboratories, Inc, 2003)
1 QLT Inc., 2005, February 17
2 10-15% growth over 5 years (Novis, 2004)
3 Based on starting point of $84M Eligard® 2004 sales (QLT Inc., 2005, January 26)
4 Atrix Laboratories Inc., 2004
5 Assume 50:50 profit sharing with Sanofi-Aventis after expenses

Appendix 8: Generic Dermatology Estimated Sales and Revenues 2005-2015

Product: Generics
Indication: Dermatology

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Assumptions:												
	Market Size ($M)[1]	2000	2100	2205	2315	2431	2553	2680	2814	2955	3103	3258
	Market Growth Rate[1]	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
	Target % of Market[2]	1%	2%	3%	4%	4%	4%	4%	4%	4%	4%	4%
	Expense % of Sales[3]	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
	Royalties[4]	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Financials:	All US$ millions											
	Total Sales	20	42	66	93	97	102	107	113	118	124	130
	Expense	4	8	13	19	19	20	21	23	24	25	26
	Net Sales	16	34	53	74	78	82	86	90	95	99	104
	Less royalties	8	17	26	37	39	41	43	45	47	50	52
	Revenues	8	17	26	37	39	41	43	45	47	50	52

Notes:

1 Theta Reports (2003)
2 Based on $30-35 million free cash flow in 2008 (QLT Inc., 2004, December 9)
3 Based on lower expense ratios for generic products from lower marketing expenses
4 Based on 50:50 partnership with Sandoz (QLT Inc., 2005, February 17)

Appendix 9: Aczone™ in Acne Estimated Sales and Revenues 2005-2015

Product: Aczone™
Indication: Acne

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Assumptions:												
	Development Stage:	Launch[1]										
	Market Size ($M)[2]	800	816	832	849	866	883	901	919	937	956	975
	Market Growth rate	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
	Target % of Market	2%	10%	20%	25%	25%	25%	20%	15%	10%	5%	2%
	Target Market growth		400%	100%	25%			-20%	-25%			
	Expense % of Sales	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
	Royalties[3]	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Financials:	All US$ millions											
	Total Sales	16	82	166	212	216	221	180	138	94	48	20
	Expense	20	29	58	74	76	77	63	48	33	17	7
	Net Sales	(4)	53	108	138	141	144	117	90	61	31	13
	Less royalties	(2)	27	54	69	70	72	59	45	30	16	6
	Revenues	(2)	27	54	69	70	72	59	45	30	16	6

Notes:

1 Launch date Q3,'05 (QLT Inc., 2004, December 9)
2 Atrix Laboratories Inc (2004, September)
3 Assumed equal profit-sharing with Astellas Pharma

Appendix 10: Aczone™ in Rosacea Estimated Sales and Revenues 2005-2015

Product: Aczone™
Indication: Rosacea

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Assumptions:												
	Development Stage:	Phase II	Phase III	NDA	Launch[1]							
	Market Size ($M)[2]	1,600	1632	1,665	1,698	1,732	1,767	1,802	1,838	1,875	1,912	1,950
	Market Growth rate	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
	Target % of Market				5%	10%	15%	20%	20%	20%	15%	10%
	Target Market growth					100%	50%	33%			-25%	-33%
	Expense % of Sales				35%	35%	35%	35%	35%	35%	35%	35%
	Royalties[3]	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Financials:	All US$ millions											
	Total Sales				85	173	265	360	368	375	287	195
	Expense	5	30	20	30	61	93	126	129	131	100	68
	Net Sales	(5)	(30)	(20)	55	113	172	234	239	244	186	127
	Less royalties	(4)	(21)	(14)	39	79	121	164	167	171	131	89
	Revenues	(2)	(9)	(6)	17	34	52	70	72	73	56	38

Notes:

1 Launch date Q3,'05 (QLT Inc., 2004, December 9)
2 Twice the market of Acne (QLT Inc., 2004, December 9)
3 Assumed partnered with Astellas Pharma

Appendix 11: Lemuteporfin in BPH Estimated sales and Revenues 2005-2015

Product: Lemuteporfin
Indication: BPH

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Assumptions:												
	Development Stage:	Phase II	Phase III	NDA	Launch[1]							
	Market Size ($M)[2]	1,000	1050	1,103	1,158	1,216	1,276	1,340	1,367	1,394	1,422	1,451
	Market Growth rate	5%	5%	5%	5%	5%	5%	2%	2%	2%	2%	2%
	Target % of Market				2%	8%	15%	15%	10%	8%	6%	4%
	Target Market growth					300%	88%		-33%	-20%	-25%	-33%
	Expense % of Sales				35%	35%	35%	35%	35%	35%	35%	35%
	Royalties[3]				5%	5%	5%	5%	5%	5%	5%	5%
Financials:	(All US$ millions)											
	Total Sales				23	97	191	201	137	112	85	58
	Expense	5	30	20	20	34	67	70	48	39	30	20
	Net Sales	(5)	(30)	(20)	3	63	124	131	89	73	55	38
	Less royalties				0	3	6	7	4	4	3	2
	Revenues	(5)	(30)	(20)	3	60	118	124	84	69	53	36

Notes:

1 Phase II start (QLT Inc., 2004, December 9); other development timelines are assumed.
2 Beck (1998)
3 Assume royalties owed to inventors or patent holders

Appendix 12: Bone Regeneration Estimated Sales and Revenues 2005-2015

Product: CP-533,536 in Atrigel® (Pfizer)
Indication: Bone regeneration

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Assumptions:												
	Development Stage:	Phase II	Phase III	NDA	Launch[1]							
	Market Size ($M)[2]	1,000	1100	1,210	1,331	1,464	1,611	1,772	1,949	2,144	2,358	2,594
	Market Growth rate	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
	Target % of Market				5%	15%	25%	35%	35%	30%	25%	20%
	Target Market growth					200%	67%	40%		-14%	-17%	-20%
	Expense % of Sales				35%	35%	35%	35%	35%	35%	35%	35%
	Royalties[3]				90%	90%	90%	90%	90%	90%	90%	90%
Financials:	All US$ millions											
	Total Sales				67	73	242	443	682	750	707	648
	Expense	1	1	1	23	26	85	155	239	263	248	227
	Net Sales	(1)	(1)	(1)	43	48	157	288	443	488	460	421
	Less royalties				39	43	141	259	399	439	414	379
	Revenues	(1)	(1)	(1)	4	5	16	29	44	49	46	42

Notes:

1 Launch date based current Phase II status (QLT Inc., 2005, January 13); other timelines are assumed
2 Market size and market growth rate are from curasan AG (2005)
3 Assume licensing agreement with Pfizer yields 10% for QLT

Appendix 13: Atrigel® - Octreotide Estimated Sales and Revenues 2005-2015

Product: Atrigel® - Octreotide
Indication: Carcinoid Tumour

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Assumptions:												
	Development Stage:	Phase I	Phase II/III	NDA	Launch[1]							
	Market Size ($M)[2]	700	714	728	743	758	773	788	804	820	837	853
	Market Growth rate	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
	Target % of Market				5%	15%	25%	35%	35%	30%	25%	20%
	Target Market growth					200%	67%	40%		-14%	-17%	-20%
	Expense % of Sales				35%	35%	35%	35%	35%	35%	35%	35%
	Royalties[3]				5%	5%	5%	5%	5%	5%	5%	5%
Financials:	(All US$ millions)											
	Total Sales				37	114	193	276	281	246	209	171
	Expense	2	30	20	20	40	68	97	98	86	73	60
	Net Sales	-2	-30	-20	17	74	126	179	183	160	136	111
	Less royalties				1	4	6	9	9	8	7	6
	Revenues	(2)	(30)	(20)	16	70	119	170	174	152	129	105

Notes:

1 Launch date based on QLT Inc. (2004, December 9)
2 Based on 2003 Sandostatin Sales (QLT Inc., 2005, January 13)
3 Assume royalties owed to inventors or patent holders

Appendix 14: Summary of QLT's Estimated Revenues and Income 2005-2015

Income from all products
All US$ millions

Financials:		**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
	Total Sales	686	781	821	1041	1371	1769	2072	1981	1766	1485	1203
	Expense	268	361	341	372	468	606	711	678	600	501	401
	Net Sales	418	420	480	669	904	1163	1361	1304	1166	984	802
	Less royalties	211	245	273	376	492	631	767	767	706	603	497
	Revenues	207	175	207	293	411	532	595	537	456	380	304
	% Net Margin[1]	31%	31%	31%	31%	31%	31%	31%	31%	31%	31%	31%
	Net income	64	54	64	91	128	165	184	166	141	118	94
	% Growth in net income (yr/yr)		-15%	19%	41%	40%	29%	12%	-10%	-15%	-17%	-20%
	Annualized average growth 2005-2010						26%					
	Income tax (34%)	64	54	64	91	128	165					
	Pre-tax income	97	82	97	138	193	250					

Risk Adjusted Growth

Assumptions:

Phase	POS	Product
Phase I/II	20%	Octreotide
Phase II	25%	BPH, Bone regeneration, Rosacea
NDA	95%	Aczone™

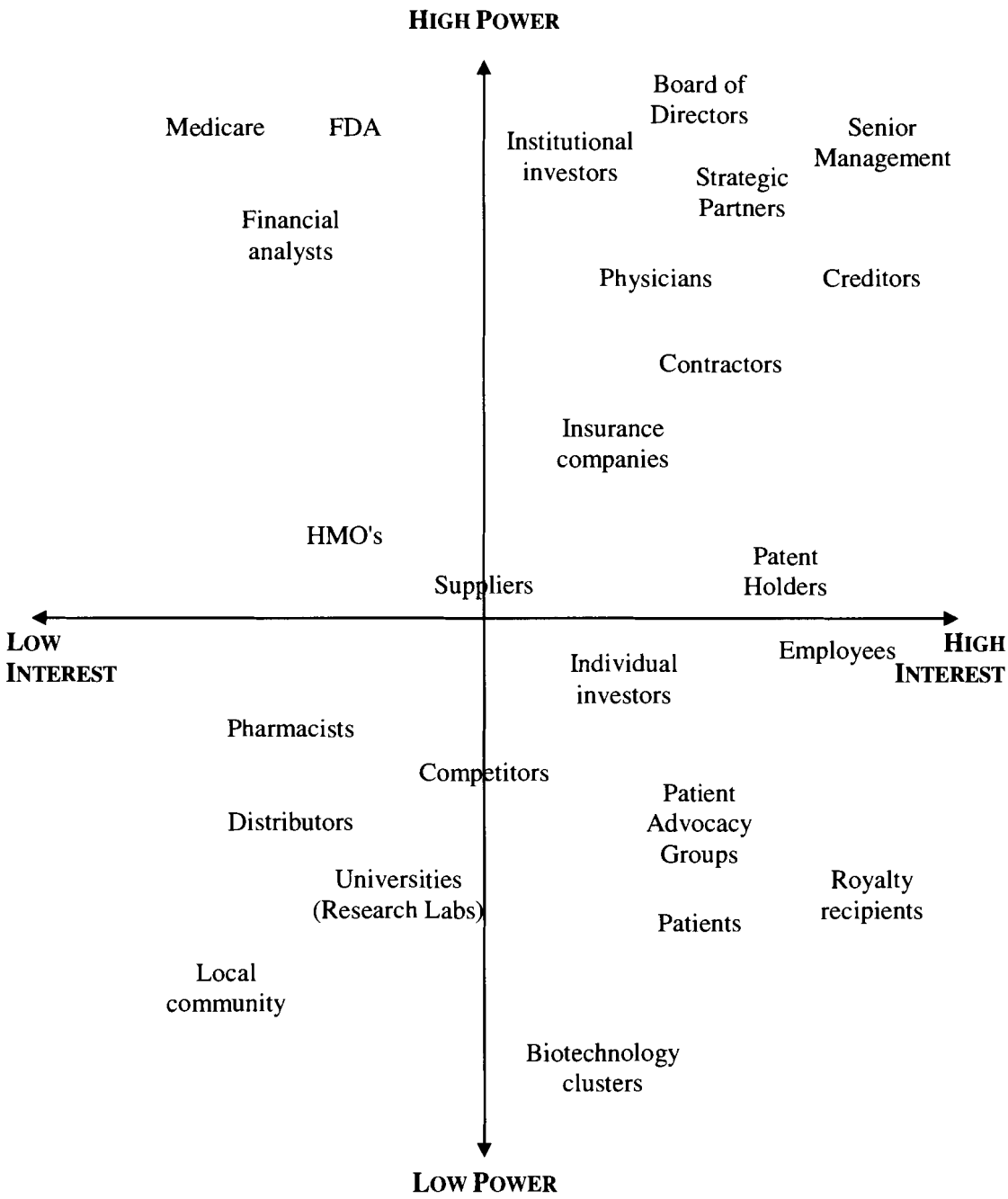
Financials:

(All US$ millions)		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
	Total Sales	685	777	815	872	904	961	959	862	717	594	487
	Expense	257	289	292	298	304	323	321	286	233	189	150
	Net Sales	428	487	523	574	600	638	638	576	484	405	336
	Less royalties	214	259	281	313	328	350	357	329	285	238	196
	Revenues	214	228	242	261	273	288	281	247	196	166	139
	% Net Margin[1]	31%	31%	31%	31%	31%	31%	31%	31%	31%	31%	31%
	Net income	66	71	75	81	84	89	87	77	61	51	43
	% Growth in net income (yr/yr)		6%	6%	8%	5%	6%	-2%	-12%	-21%	-15%	-16%
	Annualized average growth 2005-2010						6%					
	Income tax (34%)	66	71	75	81	84	89					
	Pre-tax income	101	107	114	122	128	135					

Notes:

1 From QLT net profit margin (QLT Inc., 2004, April 28)

Appendix 15: QLT's Stakeholders



Appendix 16: Financial Feasibility of Deal Candidates

In order to determine the financial feasibility of deal candidates, the following assumptions were made:

Metric	Assumption
# QLT shares outstanding	92,020,000
QLT share price	$ 13.46
QLT market capitalization	$ 1.1 billion
Deal premium	28% (based on deal premium of Atrix acquisition)*
Amount of cash offer	50% (based on ratio of Atrix deal cash offered : Atrix market capitalization when merger announced; maximum $300M)*
QLT pre-tax income	From Appendix 13, risk adjusted growth section
QLT net income	From Appendix 13, risk adjusted growth section
# QLT shares annual increase	1 million

Source: Yahoo! Financials (2005, March 3)

* QLT Inc. (2004, November). QLT cash balance as of December 31, 2004 was $380 million.

To calculate QLT's EPS prior to the deal, the QLT net income over the number of outstanding QLT shares was calculated. The forecasted EPS for QLT is:

Year	2005	2006	2007	2008	2009	2010
EPS	$072	$0.75	$0.79	$0.84	$0.87	$0.91

To calculate the EPS after the deal, the QLT net income plus the projected pre-tax income of the target company was combined over the total number of outstanding shares (QLT plus additional shares issued under the deal). The projected pre-tax income of the target company was retrieved from analyst reports.

Appendix 17: Connetics Financials and Products

Connetics Estimated Financials ($ M US)[16]

Year	2005	2006	2007	2008	2009	2010
Pre-tax income	39	109	138	172	215	269

QLT & Connetics Combined Company Estimated Financials

Year	2005	2006	2007	2008	2009	2010
Net income ($ M US)	87	136	159	186	218	258
Growth %	-	56	17	17	17	18
# outstanding shares	153,118,158	154,118,158	155,118,158	156,118,158	157,118,158	158,118,158
EPS	$0.57	$0.88	$1.02	$1.19	$1.39	$1.63

Deal Accretion/Dilution %

Year	2005	2006	2007	2008	2009	2010
QLT EPS	$0.72	$0.75	$0.79	$0.84	$0.87	$0.91
Combined EPS	$0.57	$0.88	$1.02	$1.19	$1.39	$1.63
Accretion / (dilution) %	(21)	17	29	42	59	79

Connetics Commercial Products

Product	Market	Characteristics	Q4, 2004 Sales
Luxiq	Scalp dermatoses $985 M	Mid-potency topical steroid using VersaFoam delivery	$22.6 M (with Olux)
OLUX	Scalp dermatoses and mild to moderate psoriasis $985 M	High potency topical steroid using VersaFoam delivery	

[16] *Estimate from Connetics Corporation (2005, January 25) for 2005; estimate for 2006 based on 160% growth rate, and estimates from 2007 to 2010 based on 25% growth rate.*

Product	Market	Characteristics	Q4, 2004 Sales
Evoclin	Acne	Topical clindamycin antibiotic using VersaFoam delivery	$2.9M (December only)
Soriatane	Severe psoriasis	Oral retinoid	$18 M

Source: Connetics Corporation (2005)

Connetics Pipeline Products

Product	Market	Characteristics	Phase	Launch Year
Velac	Acne	Topical gel, clindamycin antibiotic combined with isotretinoin (retinoid)	NDA approved	2005
Extina	Seborrheic dermatitis	Antifungal ketoconazole using VersaFoam	NDA submitted - non-approvable letter received early 2005	Unknown
Desilux	Atopic dermatitis	Low potency topical steroid	Phase III	2006 at the earliest[17]

Source: Connetics Corporation (2005), unless otherwise noted.

[17] Estimated from average drug development timelines, not based on any published information from Connetics.

Appendix 18: Ligand Pharmaceuticals Financials and Products

Ligand Estimated Financials ($ M US)[18]

Year	2005	2006	2007	2008	2009	2010
Pre-tax income	29	39	138	210	318	366

QLT & Ligand Combined Company Estimated Financials

Year	2005	2006	2007	2008	2009	2010
Net income ($ M US)	81	91	160	211	285	321
Growth %	-	13	76	32	35	12
# outstanding shares	146,879,822	147,879,822	148,879,822	149,879,822	150,879,822	151,879,822
EPS	$0.55	$0.61	$1.07	$1.41	$1.89	$2.11

Deal Accretion/Dilution %

Year	2005	2006	2007	2008	2009	2010
QLT EPS	$0.72	$0.75	$0.79	$0.84	$0.87	$0.91
Combined EPS	$0.55	$0.61	$1.07	$1.41	$1.89	$2.11
Accretion / (dilution) %	(24)	(18)	35	68	117	132

Ligand Commercial Products

Product	Market	Characteristics	Q3, 2004 Sales
Ontak	persistent or recurrent cutaneous T-cell lymphoma	Recombinant DNA derived protein, IV delivery	$9.9M
Targretin	cutaneous T-cell lymphoma	Oral capsule and topical gel treatments, retinoid	$6.2M

[18] 2005 pre-tax income estimated from analyst annual EPS estimate of $0.03 (Yahoo! Finance, 2005, March 7). Assumed estimated growth rates for 2006 through 2010 of 34%, 250%, 50%, 50%, and 15% respectively.

Product	Market	Characteristics	Q3, 2004 Sales
Panretin gel	cutaneous lesions of patients with AIDS-related Kaposi's sarcoma	Topical treatment, retinoid	$0.3M
Avinza	Moderate to severe pain (co-promotion with Organon)	Oral once daily, extended release opioid therapy	$28.3M

Source: Ligand Pharmaceuticals (2005)

Ligand Pipeline Products

Product	Market	Characteristics	Phase	Launch Year
Targretin capsules	Non-small cell lung cancer	Oral treatment, retinoid	Phase III	Ph III completion March 2005; estimated launch end of 2006 or early 2007 if approved[19]
Ontak	Non-Hodgkins Lymphoma	Recombinant DNA derived protein, IV delivery	Phase II	2008 at the earliest[20]
Ontak	Chronic lymphocytic leukemia	Recombinant DNA derived protein, IV delivery	Phase II	2008 at the earliest[21]

Source: Ligand Pharmaceuticals (2005)

[19] Launch estimated from average NDA review time, not based on any published information from Ligand.
[20] Launch estimated from average drug development timelines, not based on any published information from Ligand.
[21] Ibid.

Appendix 19: Cell Therapeutics Financials and Products

Cell Therapeutics Estimated Financials ($ M US) [22]

Year	2005	2006	2007	2008	2009	2010
Pre-tax income (loss)	(186)	(74)	85	220	330	495

QLT & Cell Therapeutics Combined Company Estimated Financials

Year	2005	2006	2007	2008	2009	2010
Net income (loss) ($ M US)	(57)	17	125	218	293	405
Growth %	-	-130	632	74	35	38
# outstanding shares	127,051,233	128,051,233	129,051,233	130,051,233	131,051,233	132,051,233
EPS	($0.45)	$0.13	$0.97	$1.67	$2.24	$3.06

Deal Accretion/Dilution %

Year	2005	2006	2007	2008	2009	2010
QLT EPS	$0.72	$0.75	$0.79	$0.84	$0.87	$0.91
Combined EPS	($0.45)	$0.13	$0.97	$1.67	$2.24	$3.06
Accretion / (dilution) %	(163)	(82)	22	99	157	237

[22] 2005 pre-tax income estimated from analyst annual EPS estimate of -$2.19 (Yahoo! Finance, 2005, March 7). Assumed estimated growth rates for 2006 and 2007of 60% and 210% respectively, and 50% from 2008 to 2010.

Cell Therapeutics Commercial Products

Product	Market	Characteristics	Q4, 2004 Sales	2005 Forecast
TRISENOX	Orphan drug: Acute promyelocytic leukemia, multiple myeloma, MDA, AML, CLL, CML, hepatocellular carcinoma (liver cancer)	Daily injections	$6.4M quarter	$29M

Source: Cell Therapeutics, Inc. (2005)

Cell Therapeutics Pipeline Products

Product	Market	Characteristics	Phase	Launch Year
XYOTAX	Lung cancer, ovarian cancer (third-line treatment); esophageal/gastric cancer	Protein polymer for selective delivery of paclitaxel; IV infusion	Phase III for non-small cell lung cancer; Phase II for ovarian/peritoneal cancer; Phase I for esophageal and gastric cancer	NDA submission for lung cancer end of 2005; launch by mid-2007[23]
Pixantrone	Non-Hodgkin's lymphoma	Anthracycline with lower cardiac toxicity	Phase III comparative trial for third-line treatment; Phase I/II combination studies	NDA submission 2006; launch by end of 2007/early 2008[24]
TRISENOX	Prostate cancer, Liver cancer (hepatocellular carcinoma)	Daily injections	Phase II prostate cancer; Phase I liver cancer	2008 at the earliest[25]
CT-2106	Ovarian/peritoneal cancer; colorectal cancer (second line)	Camptothecin polymer to improve solubility	Phase II for ovarian/peritoneal cancer; Phase I/II for colorectal cancer	2008 at the earliest[26]

Source: Cell Therapeutics, Inc (2005)

[23] Launch estimated from average NDA review times, not based on any published information from Cell Therapeutics.
[24] Ibid.
[25] Launch estimated from average drug development timelines, not based on any published information from Cell Therapeutics.
[26] Ibid.

Appendix 20: Barrier Therapeutics Financials and Products

Barrier Therapeutics Estimated Financials ($ M US)[27]

Year	2005	2006	2007	2008	2009	2010
Pre-tax income (loss)	(60)	(56.2)	(11.6)	32	48	71

QLT & Barrier Therapeutics Combined Company Estimated Financials

Year	2005	2006	2007	2008	2009	2010
Net income (loss) ($ M US)	23	29	63	96	110	130
Growth %	-	26	114	53	15	18
# outstanding shares	112,114,413	113,114,413	114,114,413	115,114,413	116,114,413	117,114,413
EPS	$0.21	$0.26	$0.55	$0.83	$0.95	$1.11

Deal Accretion/Dilution %

Year	2005	2006	2007	2008	2009	2010
QLT EPS	$0.72	$0.75	$0.79	$0.84	$0.87	$0.91
Combined EPS	$0.21	$0.26	$0.55	$0.83	$0.95	$1.11
Accretion / (dilution) %	(71)	(66)	(31)	(1)	9	22

[27] 2005 pre-tax income estimated from analyst annual EPS estimate of -$2.55 (Yahoo! Finance, 2005, March 7). Estimated growth rates for 2006 through 2010 are 6%, 80%, 370%, 50% and 50% respectively.

Barrier Therapeutics Commercial Product

Product	Market	Characteristics	Q4, 2004 Sales	2005 Forecast
Solage	Age spots	Topical solution	N/A	N/A

Source: Barrier Therapeutics, Inc. (2005)

Barrier Therapeutics Pipeline Products

Product[28]	Market	Characteristics	Phase	Launch Year
Zimycan	*Candida*-associated diaper dermatitis	Topical antifungal ointment	NDA	NDA submitted, launch 2nd half 2005[29]
Sebazole	Seborrheic dermatitis	Topical antifungal gel	Phase III completed	2006
Hyphanox	Vaginal yeast infection; nail fungus	Tablet formulation of antifungal agent for once-daily dosing	Phase III for vaginal yeast infection began early 2004	2007
Liarozole	Congenital ichthyosis, orphan drug status	Oral treatment	Not disclosed	Not disclosed
Rambazole	Psoriasis, severe acne	Oral formulation	Phase IIa for psoriasis	2008 at earliest
Azoline	Skin and mucosal fungal infection	Oral antifungal agent	Phase IIa	2008 at earliest
Hivenyl	Allergic reactions of the skin	Oral antihistamine	Phase I complete	2008 at earliest
Atopik	Eczema	Topical treatment	Phase I	2009 at earliest

Source: Barrier Therapeutics, Inc. (2005)

[28] Zimycan marketing rights have been allocated to Healthpoint Inc in the U.S. and Canada; marketing and distribution rights for Zimycan, Sebazole, and Liarozole, have been allocated to Grupo Ferrer International in Europe, Latin America, and Africa

[29] From Barrier Therapeutics Inc. website; all other launch years for pipeline products are estimates based on average drug development timelines rather than any published information from Barrier Therapeutics.

Appendix 21: Cell Genesys Financials and Products

Cell Genesys Estimated Financials ($ M US) [30]

Year	2005	2006	2007	2008	2009	2010
Pre-tax income (loss)	(93)	(117)	(117)	(96)	(4)	100

QLT & Cell Genesys Combined Company Estimated Financials

Year	2005	2006	2007	2008	2009	2010
Net income (loss) ($ M US)	3	(9)	(5)	14	78	150
Growth %	-	-400	-45	-380	464	92
# outstanding shares	106,313,522	107,313,522	108,313,522	109,313,522	110,313,522	111,313,522
EPS	$0.03	($0.08)	($0.05)	$0.13	$0.71	$1.35

Deal Accretion/Dilution %

Year	2005	2006	2007	2008	2009	2010
QLT EPS	$0.72	$0.75	$0.79	$0.84	$0.87	$0.91
Combined EPS	$0.03	($0.08)	($0.05)	$0.13	$0.71	$1.35
Accretion / (dilution) %	(96)	(111)	(106)	(85)	(19)	48

Cell Genesys Pipeline Products

Product	Market	Characteristics	Phase	Launch Year
GVAX Prostate	Hormone-refractory prostate cancer	Non-patient specific vaccine; intradermal injection	Phase III	2008 at earliest

[30] 2005 pre-tax income estimated from analyst annual EPS estimate of -$2.19 (Yahoo! Finance, 2005, March 7). Assumed estimated growth rates for 2006 through 2010 are -25%, 0%, 20%, 95% and 2600% respectively.

Product	Market	Characteristics	Phase	Launch Year
GVAX Lung	Non-small cell lung cancer	Patient specific vaccine	Phase II	2009 at earliest
GVAX Pancreatic	Pancreatic cancer	Non-patient specific vaccine	Phase II	2009 at earliest
GVAX Leukemia	Acute leukemia	Patient specific vaccine	Phase II	2009 at earliest
GVAX Myeloma	Multiple myeloma (11,000 deaths per year)	Patient specific cancer vaccine	Phase I/II	2009 at earliest
CG7870	Advanced stage prostate cancer	Oncolytic virus therapy; I.V. delivery with Taxotere	Phase I/II	2009 at earliest

Source: Cell Genesys, Inc. (2005), except "Launch Year", which are estimated from product development phase and average drug development timelines.

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