Carnegie Consulting

Strategic Solutions for Business

Drivers of Future Growth in the Pharmaceutical Industry

Prepared for:
Eli Lilly and Company

Lilly
Answers That Matter.

Table of Contents

Executive Summary

During the final months of 2001, Eli Lilly and Company watched anxiously as its Prozac sales plummeted with the launch of generic substitutes on August 3rd. Once Lilly's most profitable drug, Prozac sales fell 66 percent for the quarter and 23 percent for the year. Even so, Lilly took justified comfort in its 2001 performance as overall sales increased 6 percent and non-Prozac sales increased 17 percent. The first quarter of 2002 brought more discouraging news. Overall Company profits fell 22 percent as Prozac sales dropped another 70 percent. Sales of then Xigris sepsis treatment, which Lilly was hoping would help make up for the fall in Prozac sales, were less than expected. Overall Company sales fell 8.7 percent. Even so, Lilly expects its 2002 earnings to meet earlier forecasts, and its stock price actually rose on the first quarter news by $1.78 to $75.20.

At a recent meeting with financial analysts, Lilly presented its growth strategy for the next ten years. Its CEO asserted that Lilly expects to "discover or collaborate with partners on drug candidates with best-in-class or first-in-class potential and to make the investments necessary to maximize the value of those molecules." We at Carnegie Consulting believe that such plans are indeed achievable. In this study, we look at two drugs, Cialis and Forteo, to demonstrate that such growth is likely if Lilly takes the proper steps. We conclude that Cialis has potential to be a best-in-class product and Forteo has potential to be a first-in-class product. Lilly's success will depend crucially on the success of pipeline drugs such as these two products. Many industry experts rate Lilly's R&D pipeline among the best in the pharmaceutical industry. Lilly has nine late-stage compounds it anticipates launching between now and 2004. However, the Company's bright future is by no means assured. It must still play its cards right if it hopes to post strong sales growth numbers over the next decade.

Company Overview

Eli Lilly and Company will celebrate its 126th anniversary in May 2002. The Company was founded in 1876 by Colonel Eli Lilly in Indianapolis, Indiana. Frustrated by the poorly prepared and often ineffective medicines of his day, the 38-year-old pharmaceutical chemist and U.S. Civil War veteran made the following commitments to himself and to society:

- He would found a company that manufactured pharmaceutical products of the highest possible quality.
- His company would develop only medicines that would be dispensed at the suggestion of physicians rather than by eloquent sideshow hucksters.
- Lilly pharmaceuticals would be based on the best science of the day.

Business soon flourished, yet Colonel Lilly was dissatisfied with traditional methods of testing the quality of his products. As a result, in 1886, Lilly became one of the first

companies to initiate a bona fide pharmaceutical research program, hiring Ernest Eberhard, a chemist and one of the first graduates of a new pharmacy program at Purdue University, as its first scientist. Together, they would improve upon the newest techniques for quality evaluation and eventually, they would lay the foundation for the Lilly tradition: “A dedication that first concentrated on the quality of existing products and later expanded to include the discovery and development of new and better pharmaceuticals.”

Eventually, Colonel Lilly's son, Josiah K. Lilly Sr., and two grandsons, Eli Lilly and Josiah K. Lilly Jr., each served as president of the Company. Each president contributed a distinctive approach to management. These management styles have fused to establish a corporate culture in which Lilly employees are viewed as the company's most valuable assets.[i]

Some early milestones of the Company include introducing the first commercially available insulin, initiating a research program to find a treatment for pernicious anemia, being among the first to mass produce penicillin, launching the first of a long line of oral and injectable antibiotics, and developing anticancer drugs known as vinca alkaloids. In 1982, Lilly introduced Humulin®, which is insulin identical to that produced by the human body. At the time, this was considered the most significant breakthrough in diabetes care since the 1920s. Later, Lilly launched Prozac®, the first major introduction in a new class of drugs for treatment of clinical depression.

Pharmaceutical Products

The Company's pharmaceutical products include Neuroscience products, its largest-selling product group, including Prozac, indicated for the treatment of depression and, in many countries, for bulimia and obsessive-compulsive disorder; Zyprexa, a product for the treatment of schizophrenia and acute bipolar mania; the Darvon line of analgesic products; Permax, a treatment for Parkinson's disease, and Sarafem, for the treatment of pre-menstrual dysphoric disorder. Endocrine products include Humulin, human insulin produced through recombinant DNA technology; Humalog, a rapid-acting injectable human insulin analog of recombinant DNA origin; Iletin, animal-source insulin; Actos, an oral agent for Type II diabetes; Evista, a selective estrogen receptor modulator product for the prevention and treatment of osteoporosis in post-menopausal women, and Humatrope, a human growth hormone produced by recombinant DNA technology. Anti-infectives include the oral antibiotics Ceclor, Dynabac, Keflex, Keftab and Lorabid, used in the treatment of a wide range of bacterial infections, Vancocin HCl, an injectable antibiotic used primarily to treat staphylococcal infections and the injectable antibiotics Nebcin, Tazidime, Kefurox and Kefzol, used to treat a wide range of bacterial infections in the hospital setting. Cardiovascular agents include ReoPro, a monoclonal antibody product for use as an adjunct to percutaneous coronary intervention, including patients undergoing angioplasty, atherectomy or stent placement, Dobutrex, an agent for cardiac decompensation and Cynt, marketed for treatment of hypertension. Oncology products include Gemzar, indicated for treatment of pancreatic cancer and, in combination with other agents, for treatment of non-small-cell lung cancer; Oncovin, indicated for treatment of acute leukemia and, in combination with other oncolytic agents, for treatment of several different types of advanced cancers; Velban, used in a variety of

cancers; Eldisine, indicated for treatment of acute childhood leukemia that is resistant to other drugs, and an antiulcer agent, Axid.[ii]

Animal Health Products

Animal health products include Tylan, an antibiotic used to control certain diseases in cattle, swine and poultry, and to improve feed efficiency and growth; Rumensin, a cattle feed additive that improves feed efficiency and growth; Coban, Monteban and Maxiban, anticoccidial agents for use in poultry; Apralan, an antibiotic used to control enteric infections in calves and swine; Micotil and Pulmotil, antibiotics used to treat respiratory disease in cattle and swine, respectively; Surmax, a performance-enhancer for swine and poultry, and Paylean, a leanness and performance enhancer for swine. Surmax is sold as Maxus is some countries.[iii]

Business Summary

Today, Lilly is a leading global, innovation-driven, research-based pharmaceutical corporation. Incorporated in 1901, Lilly discovers, develops, manufactures and sells products in one significant business segment, called Pharmaceutical Products. The Company also manufactures and sells animal health products, and manufactures and distributes its products through owned or leased facilities. Lilly directs its research efforts primarily toward the search for products to diagnose, prevent and treat human diseases. The Company also conducts research to find products to treat diseases in animals, and to increase the efficiency of animal food production. Lilly employs more than 35,000 people worldwide and market their medicines in 159 countries. Further, Lilly has major research and development facilities in nine countries and conducts clinical trials in more than 30 countries.

Internal Rivalry

Internal rivalry refers to the interaction of firms that are trying to capture a share of the market in which they operate. All firms that constrain Eli Lilly & Co.'s strategic decisions are included in its market definition. For our purposes, we describe this market on both the macro and micro levels.

- Macro Market Description: Lilly is in the Major Drugs industry of the Healthcare Sector. The Company is engaged in the discovery, development, manufacture and sale of pharmaceutical products. Producers of generic drugs are not included in Lilly's market as the Company does not compete in generics.
    - Product: Although Lilly devotes its resources to the discovery and development of pharmaceutical products, those activities are growth drivers that add to the company's pipeline of future products. The products themselves are the patented drugs currently being sold.

- Rival Firms: Other companies in the Major Drugs industry of the Healthcare Sector that compete with Lilly in one of two ways:
  1.) Manufacturing and selling similar pharmaceutical products, and
  2.) Actively engaging in the discovery and development of new pharmaceutical products, which will help grow the company within the industry.

  Examples of such rivals are Pfizer Inc., Johnson & Johnson, GlaxoSmithKline plc, Merck & Co., Bristol-Myers Squibb Co., Novartis AG, Bayer AG, and Abbott Labs.

- Micro Market Description: With its existing product line, Lilly actively participates in four main types of pharmaceutical markets: anti-psychotic (Zyprexa), chemotherapeutic (Gemzar), diabetic, and osteoporosis preventing (Evista). Prozac, an anti-depressant, was the key revenue maker until Lilly's patent expired in August of 2001.

  - Product: We will focus on two products whose patents are pending and expected to be approved 2H 2002. For our purposes, the impact of the drugs Forteo (osteoporosis) and Cialis (erectile dysfunction) on Lilly's sales is key. (Note that Cialis will be produced by Eli Lilly & Co. and its biotechnology partner, Icos Corp.)

  - Rival Firms: There are none currently for Forteo, a natural bone-building hormone. It is a totally unique product as no current osteoporosis drug rebuilds bone matter. There will be two rivals for Cialis, Viagra (Pfizer) and Vardenafil (Bayer AG). All three drugs are distinctly different chemical entities. Each drug will enjoy patent protection for its own makeup, yet will compete in the same pharmaceutical market for alleviating erectile dysfunction. Currently, Pfizer's Viagra dominates this market. Impotence drug sales are projected to rise to $1.6 billion.

We will refer to the macro market as the "sector" or "industry" and the micro market as the "market" in order to differentiate between the two when discussing Lilly's activities and position.

Critics of the pharmaceutical industry view drug companies as having substantial monopoly power which enables them to manipulate price. The two sources of this market power are barriers to entry (patents, regulatory barriers such as the 7-8 year process of getting FDA approval) and economic barriers (large research infrastructure necessary to produce new drugs that can compete in the market). In the pharmaceutical industry as a whole, as well as in the market for individual drugs, patents create a single-source environment wherein one company produces a specific drug. Once the patent expires, the drug becomes a multiple-source drug. Lilly seeks to maintain a strong pipeline in order to stay in the single-source drug market with various drugs. As a result, for the purpose of analyzing Lilly's market, the number of sellers is extremely small. This allows a great deal of flexibility in manipulating price.

On the other hand, even when a drug is made by only one company, competitors may exist. Different drugs that treat the same medical condition are not uncommon. In fact, Cialis is one such drug. Drugs developed in order to take market share from innovative drugs are referred to as "me, too" drugs. These imitative drugs can serve as important competitors for a single source drug.

Ultimately, Lilly's main goal is not to grow existing markets in which it operates. Rather, it strives to create new markets with innovative drugs (Forteo) or take market share from other innovative drugs (Cialis). The R&D costs are extremely large in the pharmaceutical industry, thus once Lilly is committed to developing and producing a new drug, it will not turn back. In this way, the cost of R&D and the FDA regulatory barriers serve not only as entry barriers, but also as exit barriers. Thus, we examine the future prospects of the drugs in Lilly's pipeline.

Substitutes and Complements

Cialis

1. Viagra:
Viagra (generic name: sildenafil citrate), introduced by Pfizer in 1998, is the leading prescribed treatment for erectile dysfunction (ED). Nearly 10 million men in the United States have used Viagra and it has been prescribed 39 million times.[iv] Viagra brand recognition is exceptional and the drug currently takes almost 100% of the ED market. Fourth quarter sales in 2001 totaled $415 million.[v] Viagra works by inhibiting PDE-5, which allows for increased blood flow. Nearly 70% of intercourse attempts were successful in clinical trials, versus 26% with placebo.[vi] Side effects include headache, facial flushing, upset stomach, bluish vision, blurred vision, and sensitivity to light. Other downsides are that Viagra is expensive – it costs about $9 per tablet – and it takes up to one hour to reach effectiveness.

2. Vardenafil:
Vardenafil is currently being developed by Bayer AG. The drug also works by inhibiting PDE 5, but it has less side effects than Viagra and is effective when taken as little as 20 minutes before intercourse. Vardenafil will have a difficult time gaining market share because it is more similar to Viagra than is Cialis. The drug has been submitted for regulatory approval and is expected to be on the market in 2003. Bayer studies reveal that 85% of the men treated with Verdenafil experienced positive results.[vii]

3. Alternative Treatments:
Although they do not attract a significant share of the market, several alternative treatments for ED are available. These include Vacuum Erection Devices (VED) constriction rings, and penile injections (which require a prescription).

Forteo

1. Fosamax:
Fosamax (generic name: alendronate), produced by Merck, is the most commonly used medication in the category of bisphosnates. This class of medication blocks the breakdown of bone by binding permanently to the bone surfaces. The price range for a one-month supply is $41 – 80.[viii] Problems with Fosamax are that it is poorly absorbed (patients may only ingest water for 30 minutes after taking the pill), can irritate the esophagus, may not be used by women with kidney problems, and often causes heartburn. With aldendronate, spinal bone mineral density increases 4% the first year, and 5-7% the second year for women taking a 10 mg daily dose.[ix] This increase in bone mass is less than that experienced by women taking an estrogen-progesterone combination. Fosamax, however, has fewer side effects and is favored by women who are unwilling or unable to take hormone therapies. Fosamax is one of the few osteoporosis drugs that has also been approved for use by men. Sales of Fosamax totaled $1,759.2 million in 2001.[x]

2. Evista:
Evista (generic name: raloxifene), another Eli Lilly osteoporosis drug, is a selective estrogen receptor modulator (SERM). It is an estrogen-like drug (but not a hormone) that exerts a positive effect on the bones and heart, without adversely affecting the uterus and breast. Over 10 million prescriptions have been filled since the FDA approved it in 1997, and sales for 2001 were $664.8 million.[xi] The drug has positive side effects for cholesterol and cardiovascular disease. Unlike estrogen, raloxifene does not increase the risk of breast and uterine cancer, has not been shown to cause breast tenderness or vaginal bleeding, and is not associated with an increased risk for urinary incontinence. Women who are pre-menopausal or who have had liver problems or blood clots may not use Evista. Noted side effects of the drug are increased risk of developing blood clots, hot flashes, and leg cramps. A one-month supply of Evista costs $81 - 120.[xii] Eli Lilly has said that some patients may be most helped by a combination therapy of Evista and Forteo – thus, the drug is both a complement and a substitute.

3. Miacalcin:
Miacalcin (generic name: calcitonin) is a nasal spray hormone produced by Novartis Pharmaceuticals. It has been shown to reduce the pain associated with osteoporetic compression fractures and to prevent future fractures by blocking the breakdown of bone. A one-month supply costs less than $40.[xiii] The FDA approved the drug in 1995. Calcitonin is also available through injection, but there is no pill form on the market. Nasal calcitonin has been shown to increase spiral mineral bone density in the spine by 2-3% after 2 years.[xiv] The drug is very safe, has minimal side effects, and has no continuing effect on the bone after medication is stopped. Calcitonin given through injection has been shown to have a greater effect on bone mass; however, the drug has been most popular in the nasal form.

4. Actonel:
Actonel (generic name: risedronate) is a bisphosphonate marketed jointly by Proctor & Gamble Pharmaceuticals and Aventis Pharmaceuticals. It is very similar to alendronate (i.e., Fosamax), but is stronger. The cost per month falls between $41 and $80.[xv] It has been approved for the prevention and treatment of glucocorticoid-induced osteoporosis in men and women. Actonel is the first osteoporosis drug to consistently reduce vertebral fractures in patients after just one year of treatment.

5. Estrogen Hormone Replacement Therapy (HRT):
After menopause, the ovaries no longer produce estrogen; HRT is a way to replace the missing estrogen that helps to build and retain bone mass. Estrogen is available orally (Premarin, Estrace, Estratest), or as a skin patch (Estraderm, Vivelle). Progesterone is often prescribed along with estrogen to prevent uterine cancer that can be a side effect of estrogen use alone. HRT has been shown to increase spiral bone density in the spine by 2-5% after two years.[xvi] Risks of HRT include breast cancer, stroke, and blood clots in the legs.

Entry

It is important to note that on the macro level, the pharmaceutical industry can seldom be completely saturated as the development of a new product will always allow for the creation of a new "sub-market" within the industry. In addition, direct rivals may not exist at times due to patents and the overall dynamics of the pharmaceutical industry, wherein during the life of a patent, the only way to penetrate a market is to create a unique product whose effects mimic those enjoying patent protection. Lilly does not actively compete with generics. Rather, the development of new drugs through R&D and the procurement of new patents is most important.

Entry is supposed to erode incumbents' profits in two ways. First, entrants steal incumbents' business, dividing up market demand among a greater number of sellers. Second, entrants decrease market concentration, which increases internal rivalry and reduces price-cost margins. At 25.6% net profit margin, Lilly enjoys the highest net margin among the largest members of the Major Drugs industry. The most recent example of entry eroding profits has been the significant decline in Lilly's Prozac sales resulting from generic competition since the expiration of Prozac's patent in 2001.

To reiterate, patents make entry in the pharmaceutical industry quite unique. Entry into specific markets by other firms by selling the same drug (same chemical entity) is prohibited by patents. In this case entry is only possible when the patent expires. An alternative means of entry into a specific market is to discover, manufacture, and sell a unique chemical entity, which produces the same essential result as the product enjoying market dominance, by being the first mover. Lilly hopes to compete in the pharmaceutical market for alleviating erectile dysfunction by doing just this. In this case, Lilly is taking on the role as the entrant hoping to capture market share.

Lilly hopes to enjoy market dominance by being the first to develop, manufacture, and sell an osteoporosis drug that rebuilds bone for suffering men and post-menopausal women. Assuming the product goes on sale 2H 2002, Lilly may be able to capture the entire market for such osteoporosis drugs, as entry will be difficult due to patent protection. Further, there are no other osteoporosis drugs currently sold or under development that claims to rebuild bone as Lilly's does.

Buyer and Supplier Power

Buyer Power: Buyer power in the pharmaceutical industry is relatively weak. For drugs without many available substitutes, buyer power is especially low. Although large healthcare institutions such as hospitals and HMOs have some authority over drug prices because of their high volume purchases, the drug consumer is a price taker. The pharmaceutical industry is able to enjoy large margins because the weakness of entry and the existence of patent protection help maintain relatively fixed prices. Once an individual is taking a medication, their switching costs are high and their price sensitivity is very low. Buyer power is also weak because pharmaceutical companies are often able to price discriminate (e.g. discounts given to low-income senior citizens). Given the weakness of entry and the existence of patent protection, prices are relatively fixed.

Supplier Power: An assessment of supplier power takes the point of view of a downstream industry. It examines the ability of that industry's upstream input suppliers to negotiate prices that extract industry profits. Suppliers to the pharmaceutical industry include producers of laboratory, processing and safety equipment, packaging and labeling materials, chemical raw materials, and sometimes research and development services or labs that perform clinical trials. In the pharmaceutical industry, much of the supplier power comes from those individuals and institutions carrying out research and development, without which manufacture and sales are impossible. Companies that outsource their R&D are subject to significantly more upstream supplier power than those who perform R&D in house. This supplier power stems from the concentrated group of suppliers and the credible threat of forward integration. The ability of substitute inputs for R&D services is low, if not non-existent.

Strengths, Weaknesses, Opportunities and Threats

Strengths

Eli Lilly's primary strength is its innovation and ability to build a successful portfolio of major drugs. Excluding revenue losses due to the loss of the Prozac patent, Lilly sales grew 17% during fiscal year 2001.[xvii] For the most part, this growth was due to the expansion of four of Lilly's core drugs and its diabetes care products: Zyprexa, Gemzar, diabetes care products (Humulin, Humalog, Actos, and Iletin), Evista, and ReoPro. With Zyprexa leading the way with 31% year over year growth and 2001 sales of $3.1 billion, the sales for these five drugs grew 25.3% in 2001.[xviii] Due to the tremendous growth of these products, Lilly, even with major revenue losses attributed to the expiration of the Prozac patent, was able to grow revenue by 6% in 2001.[xix] Lilly was able to manage this loss by the sales of these 5 drugs growing to 61% of total company revenue in 2001 from 51.7% in 2000.[xx] Looking forward, however, the most important point regarding these core drugs is that none of these drugs have patents that expire within the next 10 or so years with $3 billion drug Zyprexa's patent expiring in 2015, Evista's patent in 2014, and Gemzar's patent in 2012.[xxi] Given the duration of these core drugs' patent

lives, Lilly should expect increased sales growth going forward as these core drugs continue to capture their respective markets and become a larger driver in Lilly's sales.

Lilly's innovative strength is represented not only in their existing portfolio of drugs, but also in Lilly's current drug pipeline that has been referred to by analysts as the "richest in the pharmaceutical industry."[xxii] In recent years, Lilly has dramatically increased their R&D spending and this spending looks to be paying off. From 2002 to 2004 (excluding the release of blockbuster Xigris in late 2001), Lilly expects to launch 9 new products currently either awaiting federal marketing approval or in late-stage testing for a wide range of unmet medical needs.[xxiii] This number of drug releases is nearly twice the number introduced in the last half of the 1990s.[xxiv] Major drugs expected to be released in the next two years include Cialis (erectile dysfunction), Forteo (osteoperosis), and Duloxetine. Substantiating a company goal of sustained long-term growth, Lilly has recently referred to its earlier-stage compounds as being "just as exciting" as their current releases. From 2004-2006, the Company expects federal approval for as many as 18 new products.[xxv] Clearly, Lilly's pipeline and its focus on continued innovation are going to be significant factors of its competitive advantages and internal strength moving forward.

Lilly's management is a major strength. 31-year Lilly veteran Sidney Taurel leads a team with a wide variety of experience, both in business and in academia.[xxvi] Lilly's board of directors even includes a Nobel Prize Winner, Dr. Steven Beering. The strength of the management lies in its commitment to producing innovation as substantiated above, building the infrastructure to fully capture rents associated with the products, and most of all accepting responsibility for the performance of the company. In the last several years, Lilly management has aggressively targeted double-digit growth moving forward. Recognizing that long-term success in pharmaceuticals is dependent on an improved pipeline and that its importance far outweighs short-term losses in net income due to increased R&D, management increased R&D expenditures dramatically in recent years including an increase of 10.7% in 2001.[xxvii] Preparing the company to fully capitalize on the nearing influx of pipeline drugs hitting the market in 2002-2004 and beyond, Lilly has added 2000 sales representatives in the previous two years and plans to increase its sales team by 5,000 or 40% in the next three.

Lilly's greatest strength regarding management is their acknowledged responsibility for the company's performance. Management at Lilly is incredibly focused on producing strong results and this focus is demonstrated by management compensation packages that are heavily weighted on the company's performance. At Lilly, more than half the pay of top executives is tied to how well the company does each year.[xxviii] When Lilly lost the Prozac patent and sales slowed, executive bonuses and stock grants were eliminated and Lilly CEO Taurel reduced his salary to $1, saying that he wanted to set an example for the company of cost-cutting and self-sacrifice.[xxix] Lilly management clearly has a vision, a means, and feels a responsibility for achieving sustained long-term growth and market value appreciation for its shareholders.

Weaknesses

A major weakness of most major pharmaceutical companies is their dependence on one or two major drugs for a significant amount of revenue. Normally, this revenue stream from a particular major drug is not interrupted until the planned expiration of the patent. However, occasionally a drug's patent is successfully challenged. When this occurs, generic products are allowed into the market and these products significantly drive down revenues for the originally patented product. When the revenues from the product compose a large portion of the company's revenue, the patent loss has a major impact on the company's bottom line and market value. Lilly's Prozac is a good example of this situation. In 2000, Prozac composed 24% of Lilly's sales and its patent was expected to expire in 2004.[xxx] However, Prozac's patent was successfully challenged and in August 2001, generic products entered the market. The effect was drastic for Lilly as Prozac sales decreased in the 4th Quarter year-over-year from $669.9 million to $225.4 million and the Company's net income for the 4th quarter dropped from .70 to .53 even though sales from other products increased.[xxxi] Currently, Lilly depends on 26.7% of its revenue from Zyprexa, a drug whose patent expires in 2015.[xxxii] Therefore, Lilly has a dependence on the drug for expected current and future income streams. Such dependence is an obvious weakness.

Firm-Specific Opportunities

The major Company-specific opportunity for Eli Lilly moving forward is to capitalize on its current portfolio of late-pipeline products. Lilly is expected to release 9 major drugs within the next 3 years and this growing product mix provides an excellent opportunity for Lilly to create a formidable base and self-fulfilling cycle with which to move forward. As stated previously, recognizing the large sales potential for these new products, Lilly management has announced that they will increase their sales force by 40% within the next three years. This larger sales force, growing product portfolio, and expected increased profitability, provides the company a significant opportunity to gain further market recognition and increased funds to expand R&D and marketing. This increased recognition and funding will allow the company greater flexibility within the pharmaceutical industry and less dependence on a few products.

Industry-Specific Opportunities

The pharmaceutical industry faces favorable world demographics in the coming years. Individuals 65 years and older use three to four times the prescription drugs used by people in their 30s.[xxxiii] Due mainly to the growing age of baby boomers in the United States, this age group will expand 17% by 2010.[xxxiv] This growth provides a significant opportunity for pharmaceutical companies to expand their U.S. sales well beyond the current $105 billion level.[xxxv] In addition, future growth should be fueled not only by an aging population, but also by population growth in the U.S.

The creation of improved drugs will fuel pharmaceutical industry growth. As scientific research continues and new products build off current products, pharmaceutical companies will create increasingly successful and novel drugs. These drugs will treat diseases for which current therapies are inadequate. These improved drugs will provide better care for individuals and serve to increase the average human's lifespan. This

increase in lifespan will intern propel the growth of the pharmaceutical industry as people live longer and require more health products.

A more efficient patent approval system will increase the market for prescription drugs. Currently there is a time differential between the submission of a drug to the FDA and its approval. However, this lag has been greatly reduced in current years. Between 1987 and 1993, an average drug application took on average 26 to 32 months before it was approved. By 1999, the approval time had decreased to only 12.6 months.[xxxvi] This trend is expected to continue as the FDA become even more efficient in future years. This decrease in drug approval time has a positive impact on pharmaceutical companies because this quicker approval process increases the duration of patent protection. Patents begin when an application is submitted. Hence, when the period between the time the drug application is submitted and the time it is approved is reduced, the effective patent duration is increased. And, this increased period of exclusivity for producing and marketing their products increases the revenues from the patent.

Threats

Eli Lilly faces a continued FDA inspection of their plants due to production flaws.[xxxvii] Originally the flaws were discovered in November, and Lilly had two months to improve its quality control. But, even after two more months, the company still failed its review. This inspection has delayed the release of the injectable form of Zyprexa and Forteo and has created uncertainty as to when they will be released. In addition, this development has created doubt regarding the planned release time of other highly touted late-stage pipeline drugs.[xxxviii] Delays in product releases negatively impact the present value of the cash flows from the products. Thus these delays, along with future unexpected product release delays, will negatively impact Lilly's market value.

Another major threat regarding the pharmaceutical industry is the industry's freedom from increased government restrictions involving the pricing of products. Drug companies depend heavily on the freedom to price their drugs effectively in order to collect the economic rents associated with exploiting their product's patent protection. Drug companies spend on average $500 million in R&D and marketing costs per drug that they distribute on the market.[xxxix] Therefore, it is important for them to be able to charge a significant premium to the marginal cost of the product in order to recoup these costs. However, health care providers are becoming increasingly stringent regarding these costs and the U.S. government has begun to take action to reduce the prices of particular products. Recently, the U.S. government forced Lilly competitor Bristol Myers to price their Cipro tablets at $.95 compared to their list price of $4.00 per dose.[xl] The government was reacting to the Anthrax outbreak when they forced the company into the new pricing by threatening to break the patent if they did not. The start of a trend toward the government controlling the price of certain products will have a lasting adverse effect on the pharmaceutical industry. Although the threat is not currently serious, it is worth noting.

Financial Outlook

Eli Lilly and Company is engaged in the discovery, development, manufacture and sale of pharmaceutical products. For the fiscal year ended 12/31/01, net sales rose 6% to $11.54 billion. Net income before extraordinary item fell 8% to $2.81 billion. Revenues reflect increased sales of Zyprexa, Evista, Gemzar, Humalog and Actos. Earnings were offset by higher research and development expenses and $311.9 million in acquired in-process R&D and asset impairment charges.[xli]

Goldman Sachs analysts expect 2002 to be a challenging year. Pricing pressures, R&D productivity issues, and cash reinvestment risks are expected to be ever present. Valuations for the pharmaceutical industry as a whole are compressed. Much of Lilly's market success depends on the timely launch of its pipeline products, Cialis and Forteo being two very important pending launches.

Lilly's market capitalization is over $83.5 billion. The Company is not highly levered and does not have any pressing debt issues. In fact, annual interest expenses are less than $184 million and long term debt is under $2.8 billion.

On January 42, 2002, Eli Lilly and Company announced its financial results for the fourth quarter and full year of 2001.

4Q 2001 highlights are as follows[xlii]:

- Sales decreased 5 percent, to $2.829 billion, compared with $2.978 billion in 4Q 2000. Excluding Prozac®, sales increased 15 percent.
- Gross margins as a percent of sales declined by 1.0 percentage point, to 80.0 percent, due primarily to the decrease in Prozac sales.
- Research and development expenses increased 8 percent, to $589.9 million, due to the company's investment in its product pipeline.
- Taking advantage of lower 4Q 2001 interest rates, Lilly refinanced and recorded as an extraordinary item, a charge of $19.7 million ($12.8 million net of tax) for early retirement of existing higher cost debt.
- Reported net income and earning per share decreased 25 percent and 24 percent, respectively, to $575.4 million and $.53 per share. These results compare with $767.3 million and $.70 per share in 4Q 2000.

2001 Annual highlights are as follows[xliii]:

- Sales increased 6 percent, to $11.543 billion, compared with reported sales of $10.862 billion in 2000. Excluding Prozac®, sales increased 17 percent.
- Zyprexa®, Lilly's breakthrough product for schizophrenia and bipolar mania, became the company's first product to surpass $3 billion in annual sales. This is just five years after the drug's launch in increasingly competitive antipsychotic and mood stabilization markets.
- Gross margins as reported increased by 0.2 percentage points, to 81.3 percent.
- Market and administrative expenses increased 6 percent, to $3.417 billion due to sales force expansions and increased marketing efforts in support of the company's growth products and upcoming product launches.

- Research and development expenses increased 11 percent, to $2.235 billion, as Lilly continued to invest in its product pipeline.
- Reported net income and earnings per share decreased 9 percent, to $2.780 billion and $2.55 per share, respectively. These results compare with reported earnings of $3.058 billion and $2.79 per share in 2000.

Pharmaceutical Product Sales Highlights - As Reported

(Dollars in millions)	Fourth Quarter		% Change Over/(Under)	Full Year		% Change Over/(Under)
	2001	2000	2000	2001	2000	2000
Zyprexa	$900.4	$695.8	29%	$3,086.6	$2,349.5	31%
Diabetes Care Products	548.0	465.7	18%	2,126.0	1,761.3	21%
Prozac, Prozac Weekly™ and Sarafem™	225.4	669.9	(66%)	1,990.0	2,573.7	(23%)
Gemzar®	200.9	160.2	25%	722.9	559.3	29%
Evista®	165.8	145.7	14%	664.8	521.5	27%
ReoPro®	105.5	105.6	0%	431.4	418.1	3%

Summary of Fourth-Quarter Earnings per Share

	2001	2000	Over/(Under)
E.P.S. (as reported, diluted)	$.53	$.70	(24)%
Add back one-time charges:			
In-process research & development	.06		
Early retirement of debt	.01		
E.P.S. (normalized, diluted)	$.60	$.70	(14)%

Summary of 2001 Earnings per Share

	2001	2000	% Over/(Under)
E.P.S. (as reported, diluted)	$2.55	$2.79	(9)%
Adjust for Y2K-related sales:		.06	
Eliminate one-time gains:			
Sale of Kinetra		(.20)	
Add back one-time charges:			
In-process research & development	.11		
Asset impairments and other site charges	.07		
Early retirement of debt	.03		
E.P.S. (normalized, diluted)	$2.76	$2.65	4%

Financial Expectations[xliv]

For the 2002 fiscal year, Eli Lilly and Company anticipates earnings per share to be in the range of $2.70 to $2.80, compared with normalized 2001 earnings per share of $2.76. Lilly expects a decline in earnings per share in the first half of 2002 followed by a return to earnings growth in the second half. For 2003, the Company targets high-teens earnings-per-share growth.

Lilly hopes to post sales growth in the low-to-mid single digits in 2002. Several key products must contribute to this growth. They include Zyprexa, Gemzar, Evista, diabetes care products and Xigris. Growth in all these products is anticipated to offset the decline of Prozac sales and anti-infectives. Lilly's plans also include a number of new product launches, including Forteo, Cialis™, atomoxetine, and duloxetine. The approval of Zyprexa IntraMuscular and Forteo as well as additional new products is dependent on resolution of all manufacturing issues to the FDA's satisfaction.

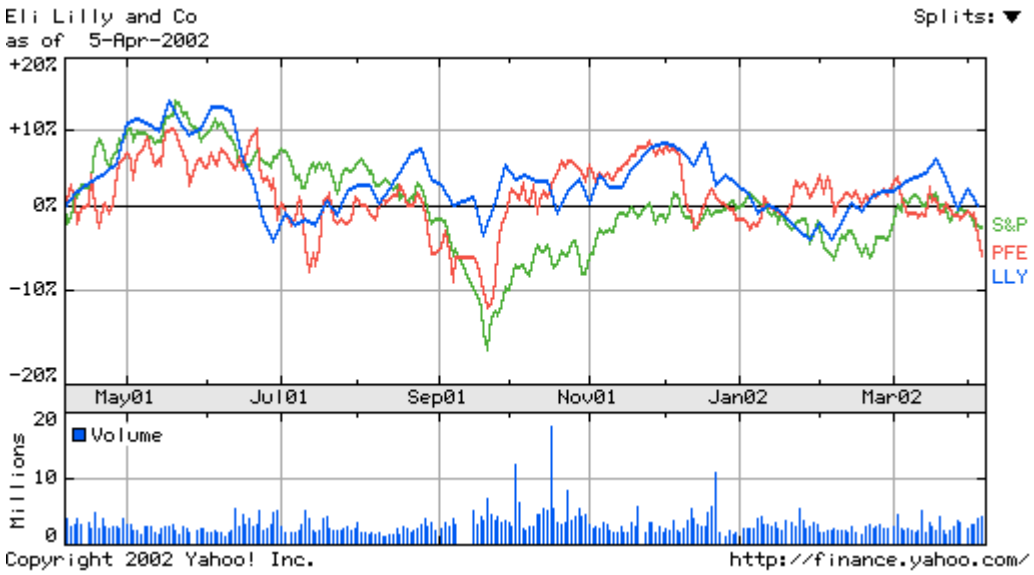
Gross margins as a percent of sales are expected to decline in 2002 approximately 1.0 percentage point as a result of the decline in Prozac sales. The Company anticipates marketing and administrative expenses to grow in the mid-high single digits. Research and development expenses are expected to grow in the low single digits. Non-operating income is expected to contribute up to $100 million in 2002.

Market uncertainty exists because there can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. Lilly's results may also be affected by such factors as: the continuing impact of generic fluoxetine on Prozac sales in the United States, competitive developments affecting current growth products, the timing of anticipated regulatory approvals and launches of new products, other regulatory developments involving current and future products, the impact of governmental actions regarding coverage and reimbursement for pharmaceuticals, and the impact of exchange rates.

ELI LILLY AND COMPANY
Operating Results (Unaudited)
(Dollars in millions, except per share data)

	Three Months Ended December 31		Twelve Months Ended December 31	
	2001	2000	2001	2000
Net sales	$ 2,828.9	$ 2,977.7	$11,542.5	$10,862.2
Cost of sales	566.7	565.2	2,160.2	2,055.7
Research and development	589.9	545.1	2,235.1	2,018.5
Marketing and administrative	882.7	944.3	3,417.4	3,228.3
Acquired in-process technology	100.0	--	190.5	--
Asset impairment and other site charges	--	--	121.4	--

Operating income	689.6	923.1	3,417.9	3,559.7
Interest expense	(22.8)	(45.9)	(146.5)	(182.3)
Other income - net	74.5	106.5	280.7	481.3
Income before income taxes and extraordinary item	741.3	983.7	3,552.1	3,858.7
Income taxes	153.1	216.4	742.7	800.9
Income before extraordinary item	588.2	767.3	2,809.4	3,057.8
Extraordinary item	(12.8)	--	(29.4)	
Net Income	$ 575.4	$ 767.3	$ 2,780.0	$ 3,057.8
Earnings per share - basic:				
Income before extraordinary item	$ 0.54	$ 0.71	$ 2.61	$ 2.83
Extraordinary item	(0.01)	--	(0.03)	--
Net income	$ 0.53	$ 0.71	$ 2.58	$ 2.83
Earnings per share - diluted:				
Income before extraordinary item	$ 0.54	$ 0.70	$ 2.58	$ 2.79
Extraordinary item	(0.01)	--	(0.03)	--
Net income	$ 0.53	$ 0.70	$ 2.55	$ 2.79
Dividends paid per share	0.28	0.26	1.12	1.04
Weighted-average shares outstanding (thousands)	1,077,305	1,079,807	1,077,497	1,081,559
Weighted-average shares outstanding (thousands) - diluted	1,090,438	1,096,384	1,090,793	1,097,725



Eli Lilly's market performance in 2001 and early 2002 was very similar to the market itself. The pharmaceutical Company's beta has been very low. However, future performance has become increasingly uncertain with the influx of generic fluoxetine and the current position of Lilly, wherein performance has become tied to the successful launch and flourishing sales of current pipeline products. In order for growth to continue in a manner expected by Lilly management, such growth products and pending launches must occur with little conflict. The Company's increasing expenditure on marketing and R&D can be seen as an investment for future growth. For the sake of all shareholders, that investment must produce a very positive return in the form of successful sales for products such as Cialis and Forteo.

Strategic Analysis: Keys for Future Growth

For the 9 months ended 9/30/01, net sales rose 11% to $8.71B. Net income before extra item fell 3% to $2.22B. Earnings were offset by $121.4M in asset impairment and other site charges and a $90.5M charge for acquired technology. As noted, severe erosion of sales in Prozac as a result of generic competition resulted in Eli Lilly and Company being able to muster only a 2% sales growth in the third quarter of 2001, which led to a 7% decrease in EPS.

It is obvious that the company is trying to make up for lost Prozac revenues by selling other products. In addition, they have consistently spent more money on R&D and technology acquisition in hopes of bolstering their pipeline for the coming years. We are focusing on two such drugs in the later stages of FDA approval. The main question and concern is whether the potential revenues from such drugs are sufficient to warrant Lilly's increased expenditures on R&D. Further, will new sales replace revenues lost

from expiring patents and increasing competition? To answer this question, we first look to the potential market for Cialis and Forteo, two drugs expected to hit the market in 2002.

Market for Cialis

Eli Lilly's Cialis, a new oral-treatment for Erectile Dysfunction (ED), will have two main competitors: Viagra, produced by Pfizer (currently in market), and Vardenafil, produced by Bayer AG (aims to be released in late 2002).

Cialis vs. Viagra

1. Cialis is able to help men with diabetes related ED (diabetes makes them very difficult to treat); 64% of users experienced improved erections vs. 25% with placebo
2. Cialis duration is longer as it lasts 24 hrs. vs. 4 hrs. for Viagra; it only takes 30 minutes for arousal while Viagra takes 1 hr.
3. Cialis has fewer side effects than Viagra's, which include common headaches, nasal congestion, flushed faces and blue vision
4. Cialis is more potent so it can be taken in smaller doses
5. Cialis shows 88% improved erections to 28% placebo (Viagra works on app. 75% of new users)
6. Viagra's advantages are its superior brand, and customer base. Viagra has also been extensively tested
7. Cialis production is partnered with marketing partner ICOS

Cialis vs. Vardenafil (note: there is not much product differentiation but Bayer AG seems to have an advantage in European marketing due to a huge partnership)

1. Similar results - Cialis has been tested further and is expected to have an earlier entry date
2. Vardenafil is focused more on the penis only as opposed to affecting the whole body
3. Bayer AG is partnered with Europe's largest drug-maker Glaxo

Important Facts –

1. 152 million men world-wide have ED
    a. 30 million U.S. men
    b. 10 million have tried Viagra
2. 150 million men world-wide have diabetes
    a. 25-75% of men with diabetes experience ED
    b. Viagra works poorly for these men
3. Viagra
    a. 50% don't renew subscriptions, it does not work on 25%
4. Analysts estimate by 2005, ED market will expand to between $3-5 billion
    a. UBS estimates Viagra will increase revenue only from $1.55B to $1.65 billion in 2005

Cialis market in 2005:

Our Assumptions:

1. Growth of ED market estimated by analysts is a proxy for the ED market's gains due to increased marketing for ED products, increased accessibility of the products, and increased acceptability of the products, etc.
2. Price of Viagra per unit stays constant from 2002-2005
3. The three companies have equal strength in international markets
4. Rate of growth in market size is equal to the rate of growth in users
5. No tangible difference between the results of the two new drugs, their marketability, or their price once they reach the market - hence it should be a toss-up choosing between them

Calculations:

- 150 million worldwide have ED (13 million already tried it, with 6.5 million not renewing Viagra subscription)
- 75 million men world-wide have diabetes related ED (150*((75+25)/2)
- So, of the 150 million men world-wide that have ED, half of them have diabetes and, therefore, dominantly prefer either new drug to Viagra
- 13/150=.087, so roughly 9% of men world-wide have tried Viagra
- Analysts expect the market to grow by (((5+3)/2)-1.55)/1.55=158%
- Using assumption #4, this means that by 2005 23.2% of the population with ED or 34.8 million people will be using an ED enhancement (notice there is still room for considerable growth)
- Much of this growth in market exploitation will be due to the growth in usage by diabetic men who are not currently being serviced (due to assumption #5, the 2 new drugs will evenly split these users)

For a simple market size, we can take the average size of the market that the analysts expect in 2005, which turns out to be $4 billion, minus the $1.6 billion that UBS expects Viagra to take in (which may be less due to its weaker product; however, it is still realistic to assume that it will maintain this position due to its dominant brand and familiarity with users). We have determined that the two new drugs are non-differentiable and are probably experienced drugs like Viagra, thus, they will split the remainder of the market - (2.4/2) = $1.2 billion market in 2005 for each of these drugs. The two new drugs will have taken advantage of several things: 1) Viagra did not meet the needs of half the market for ED (the ones with diabetes), 2) because 50% of Viagra subscriptions were not renewed, they took advantage of these 6.5 million customers who had admitted that they needed help but were not satisfied with Viagra, and 3) that they have a superior product.

It is reasonable for roughly 20-25% of individuals with ED to be treated by 2005. If prices per unit of these drugs stay constant relative to each other, then this is a valid estimate. Beyond 2005, the two new drugs will probably continue to gain on Viagra.

Potential hindrances do exist. Price per unit will inevitably fall as three major drug companies compete in a single market. This will markedly drive down the profitability of

the drug. Further, Lilly has been hurt by FDA inspection of its plants and findings of production flaws. If the release of Cialis is delayed, they will enter the market at a disadvantage because Vardenafil will have a head start in the quest against Viagra.

Market for Forteo (US Market)

We limit our study of Forteo to the US Market due to the uniqueness of the drug. Although it treats a very common disease, Forteo's effect of regenerating bone matter for osteoporosis sufferers is a bold claim. Eli Lilly will likely market the drug extensively at home, where it already has a loyal base of osteoporosis drug users (Evista - $123.8 million in domestic sales for 2001), before pushing it abroad.

The total number of potential osteoporosis sufferers over age 50 is 44 million.[xlv] Note that osteoporosis does affect individuals younger than 50, but it is a very small (probably negligible) number. It seems this number will continue to decrease as awareness of the disease spreads and more preventative measures are taken. Currently:

- 10 million have the disease
- 34 million have low bone density and are "at risk"
- Assume that 50% of "at risk" individuals will develop osteoporosis

The total number of current osteoporosis sufferers is 27 million.

- # men (20%)[xlvi]: 5.4 m
- # women (80%)[xlvii]: 21.6 m

Our Assumptions:

1. Women are more likely than men to seek treatment at an early stage because osteoporosis is usually diagnosed later in men
2. Since the men who are affected by osteoporosis are less likely to have taken preventive measures, we believe that they will be more severely affected and more likely to require drug therapy
3. Based on the above assumptions, we will say that women and men are equally likely to seek drug therapy
4. Most osteoporosis sufferers will seek treatment
5. Some individuals will oppose treatment because of their opposition to medication in general (i.e., prefer holistic medicine, etc.)
6. Some individuals will not seek treatment because they do not know they have osteoporosis or have been misdiagnosed

Supposing that 80% of osteoporosis sufferers will seek some type of drug treatment, we have the following results:

- # men sufferers seeking treatment: 4.3 m
- # women sufferers seeking treatment: 17.3 m

Dr. Felicia Cosman of Helen Hayes Hospital in West Haverstraw, N.Y., clinical director of the osteoporosis foundation, estimates that 25 – 30% of osteoporosis patients might be considered for treatment with the new drug (we assume here that Forteo will be approved for men). If this is true:

- # men considered for treatment: 4.3(.25) = 1.1 m
- # women considered for treatment: 17.3 (.25) = 4.3 m

Although Forteo is medically appropriate for the number of men and women stated above, not all individuals will choose it as they may be eligible for a variety of treatments.

Fewer treatments are available for men. Possible treatments include Fosamax and Actonel. Thus, it would seem that a higher percentage of men would choose Forteo. However, because women have more treatment options, a smaller percentage will choose Forteo.

- Assume that 45% of male sufferers will choose Forteo.
  - # men who will use Forteo: 1.1(.45)=.495 m
- Assume that 25% of female sufferers will choose Forteo.
  - # women who will use Forteo: 4.3(.25)=1.075 m

These results indicate that within the osteoporosis care segment, 1.57 million people will use Forteo. Given Evista's $165.8 million total sales for 2001, this number may not be terribly off the mark. Also, there is no other drug currently on the market or pending approval that claims to regenerate bone in osteoporosis drug users as Forteo does. Given the uniqueness of the drug and Lilly's strength as a drug supplier in the osteoporosis care segment, Forteo may prove to be a very strong addition to Lilly's lineup. However, Forteo's launch has been directly affected by Lilly's failure to meet FDA regulations in its inspection of production facilities. Forteo's launch was originally scheduled for 4Q 2001. Until Lilly resolves all manufacturing issues to the FDA's satisfaction, we consider the Company to be losing money on a drug ready to be sold to the public as it sits in Lilly's storage instead of in hospitals and pharmacies nationwide. Forteo approval is contingent upon completion of labeling negotiations and agreement on measures to ensure appropriate use of the product.

Recommendations

Lilly received a Form 483 outlining 50 additional observations from the FDA following its reinspection of certain Lilly manufacturing facilities in Indianapolis in connection with pending new-product approvals for Zyprexa® IntraMuscular and Forteo™. As noted before, Lilly management expects to post sales growth in the low-to-mid single digits in 2002. This is a very reasonable expectation. However, management tends to be optimistic in their hopes for the future. Thus, Lilly's hopes for such small growth is cause for concern. The Company will continue to lose sales in Prozac as generics capture more of the market. Timing for anticipated regulatory approvals is crucial. We at Carnegie Consulting believe that Cialis can be very successful in the erectile dysfunction market. However, Lilly must make sure that the product is launched before or as close to Vardenafil's launch. Otherwise, it will be difficult to compete effectively. Also, given

that Forteo should have already been approved, the sooner Lilly satisfies the FDA, the sooner they will capitalize on the drug.

Analysts note that one of Lilly's weaknesses in the past has been its marketing and effective sales. To capitalize on new products, Lilly is building its sales and marketing capabilities and investing in a significant sales force expansion. Lilly plans to add more than 5,000 additional sales reps worldwide over the next three years. This will double Lilly's global sales force during the five-year period from early 2000 through 2004. Further, the company will continue to in-license and co-develop products to further strengthen its pipeline. Lilly's partnership with ICOS in the production of Cialis may prove to be advantageous.

The purpose of our focus on Cialis and Forteo has been to illustrate Lilly's potential for future growth via its extensive pipeline. By studying the potential market for Cialis and Forteo, it is clear that Lilly is sitting in a prime position to greatly increase revenues over the next ten years. If we extrapolate our findings on these two drugs to the rest of Lilly's pipeline, potential for future growth seems all the more impressive. The Company's current pipeline is as follows:

Targeted first launch in 2002	
Forteo	*Osteoporosis*
Cialis™	*Male erectile dysfunction*
Atomoxetine	*Attention-deficit hyperactivity disorder (ADHD)*
Duloxetine	*Depression*
Targeted first launch in 2003	
Alimta®	*Mesothelioma*
Duloxetine	*Stress urinary incontinence*
Targeted first launch in 2004/2005	
Protein Kinase C beta (PKCÎ_) inhibitor	*Diabetic retinopathy (in Europe)*
OFC (olanzapine-fluoxetine combination)	*Treatment-resistant depression*
LY900003 (formerly ISIS 3521)	*Non-small-cell lung cancer*
Resiquimod	*Genital herpes*

On the other hand, due to the collapse of Prozac sales and Lilly's ongoing problems with the FDA, Wall Street professionals have been greatly divided in their opinions of the Company. Eight analysts have rated Lilly stock a strong buy, while fifteen others have rated it a hold. We believe that 2002 is an extremely important transition year during which the Company must reestablish compliance with federal regulators regarding quality control systems at production facilities. Failing to do so will not only delay the all-important pipeline, but may also bias the FDA advisory panel against Lilly products.

The Company has increasingly made efforts to collaborate with other companies to enhance distribution of current drugs and to co-develop new drugs. Recently, Lilly signed an agreement with 3M to collaborate on the development and commercialization of Resiquimod, which is in Phase III clinical trials for the treatment of genital herpes. The Company also announced a strategic agreement with Isis Pharmaceuticals to develop antisense compounds to be used in the treatment of cancer. Lilly has licensed

the lead compound in this collaboration, ISIS 3521. Further, Lilly has established a distribution agreement with Syncor. This will make Lilly's Xigris available to any U.S. hospital within three hours. Finally, Lilly has made efforts to collaborate with privately owned French firm Bioproject in order to develop Fasidotril, a vasopeptidase inhibitor for the treatment of congestive heart failure and hypertension. Lilly should continue to develop these types of relationships. They have not in the past and we believe that the Company's inability to maximize potential synergies has prevented it from attaining double-digit growth numbers.

Drug companies have a reputation of being reliable profit machines. The aging U.S. population and increasing lifespan will add to the industry's success. Lilly's unusual circumstances have led investors to keep a watchful eye on the Company. The necessary steps are being taken by management to prepare Lilly for future growth. However, we must reiterate that all efforts will be in vain unless the Company can ensure timely product launches. There have always been concerns that there are regulatory delays in the United States. Eli Lilly and Company must be careful not to jeopardize its position by giving the FDA a reason to further those delays.

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