HONORS CAPSTONE IN BUSINESS

Big Pharma's 2009-2013 Patent Cliff

A Comparison of Company-Level Responses and Strategic Recommendations for Pfizer, Inc. and Eli Lilly and Company

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Spring 2010

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EXECUTIVE SUMMARY

The pharmaceutical industry faces an unprecedented number of patent expirations for its pharmaceutical products between 2009 and 2013. Due to impending generic competition, the industry expects to lose 18% of total sales, equal to roughly $137B. After conducting thorough research of the industry, it is apparent that large-cap companies in the pharmaceutical industry (also known as Big Pharma) have made strategic decisions to combat the anticipated losses. This report will provide an overview of industry trends, followed by an in-depth look at two key industry competitors: Pfizer, Inc. and Eli Lilly and Company. Short-term and long-term strategic recommendations follow each company's analysis.

In preparation for the impending patent cliff (defined as a large loss of revenues due to expiring patents) the pharmaceutical industry's top management teams launched initiatives to bring down costs and increase revenues. Many of the industry's largest firms have focused on mergers and acquisitions in an attempt to bring about cost synergies and product diversification. Other firms have implemented strategic goals to diversify into biologics, which have little generic competition in the U.S. market. Despite the strategic initiatives, the pharmaceutical industry is prepared to lose a large share of revenues to generic competition.

Pfizer, the largest company in the pharmaceutical industry, will lose roughly 32% of revenues due to patent expiration. Pfizer's management has focused on mostly inorganic solutions to the revenue loss. These solutions include a cost-cutting initiative and increased activity in the M&A arena (most notably, Pfizer's mega-merger with Wyeth).

To ensure that Pfizer's efforts focus on long-term growth, as well as short-term revenues, the strategic recommendations offered in this analysis look to decrease the likelihood of future patent cliffs. In the short-term, it is important that Pfizer focus on generics and that they increase R&D expenditures. Long-term recommendations include further diversification into consumer healthcare, decreased reliance on blockbuster drugs and increased expansion into emerging markets.

Compared to Pfizer, Eli Lilly will lose roughly 40% of their annual revenue to generic competition by 2013. To combat this loss, current management launched restructuring efforts, increased R&D expenditures, incorporated biologics as a key product area, and launched a cost reduction effort.

Lilly's corporate strategy plays a perfect juxtaposition to Pfizer's outlook. Most of Lilly's strategy involves long-term, organic growth, opposed to Pfizer's short-term inorganic growth. In order to ensure that Lilly overcomes the short-term patent cliff, this analysis offers recommendations that call for immediate improvements.

After a full assessment of both company's strategic outlook and planning, it is essential that both firms follow this report's strategic recommendations to strengthen their businesses in the short and long-term.

INTRODUCTION

Often times, it is easy to expect innovation in business. This is especially true in industries such as electronics, software and pharmaceuticals. What happens when the innovation dies down and massive loss of revenue looms due to legal implications? This nightmare scenario is what the pharmaceutical industry faces from 2009 to 2013. A decrease in innovation combined with a massive patent cliff may leave the industry crippled. This report intends to shed light on this upcoming scenario and offer some strategic recommendations for two specific companies, Eli Lilly and Company and Pfizer, Inc. These two companies have opted into different strategic paths to counterbalance their upcoming losses, making them a perfect case study for this proposal. Pfizer, the largest pharmaceutical firm in the world, has looked towards inorganic growth as the main solution to their problems, while Lilly, a much smaller company than Pfizer, has elected to promote organic growth through research and development.

INDUSTRY OVERVIEW

Worldwide revenues for the pharmaceutical industry in 2009 were upwards of $760B.[1] Despite total revenue growth - heavy competition, strict regulations and rising demand for low cost drugs has put increasing pressure on the industry's major competitors.

Major Competitors

The list of large-cap pharmaceutical companies remains long, but includes companies such as Pfizer, Roche, GlaxoSmithKline, Novartis, Sanofi-Aventis, AstraZeneca and many others. Firms that have made a large impact in the rapidly growing generic market include Teva Pharmaceuticals, Sandoz (subsidiary of Novartis), Watson Pharmaceutical, and Ranbaxy

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[1] Saftlas, Herman. "Industry Survey: Healthcare: Pharmaceuticals." Standard and Poor's, 03 Dec. 2009.

Laboratories. Finally, the largest firms that exclusively deal in biotechnology include Amgen Inc., Gilead Sciences, Celgene Corporation, Biogen Idec Inc, and Genzyme Corporation.

Major Drug Markets

Within the pharmaceutical industry, several major product and disease areas receive more focus, in terms of research and development, because of their potential growth in the marketplace. One key product market is for drugs that treat cardiovascular issues such as heart attacks, hypertension and angina. It is no wonder that this product area is a primary focus for R&D, since one in five Americans suffer from a cardiovascular problem and cardiovascular disease accounts for 30% of all deaths in the developed world. Oncology is another area of focus for Big Pharma who expect the demand for products to grow to nearly $70B by 2014, accounting for roughly 9% of industry sales. Other key areas include treatments for central nervous system diseases, diabetes and Alzheimer's disease.[2]

Pharmaceuticals and Biologics

As pharmaceutical firms look to diversify their product offerings, a growing industry trend is the movement into biologics. Biologics and pharmaceuticals both help treat diseases, but it is extremely important to understand the underlying differences in the product categories. Pharmaceuticals are treatments that are "chemically synthesized and their structure is known."[3] Biologics are treatments derived from biological methods and are composed of "sugars, proteins, or nucleic acids…or may be living entities such as cells and tissues."[4] The scientific distinction is important, but the legal distinction in the United States is what makes the difference in these

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[2] Ibid, Saftlas Dec 2009.

[3] United States. Food and Drug Administration. Center for Biologics Evaluation and Research. *What Are "Biologics" Questions and Answers*. Web. 3 Apr. 2010. <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm1330 77.htm>.

[4] Ibid, US FDA Biologics.

treatments essential to a business. Pharmaceutical products receive a twenty-year exclusivity patent from the date of molecular discovery.[5] This often results in eight to fourteen years of exclusive sales rights.[6] Biologics are subject to the same patent term as pharmaceuticals, but there is no FDA pathway or guidelines in place for the approval of biogenerics.[7] This is because biologics are unique entities and cannot be easily copied and produced like generic pharmaceuticals. The result has been very few approvals for biogeneric products and thus a theoretical limitless patent for biologic drugs. While there have been talks in Congress about creating a potential biogeneric pathway and several representatives introduced a bill in the House of Representatives, movement has slowed shown by the absence of a biogeneric clause in the final version of the 2010 Obama healthcare legislature.

Outside of the United States, the European Union has implemented a pathway for biosimilar products.[8] As of 2008, there have been five biosimilar products released in the EU, with estimated annual savings of $2.5B.[9] Furthermore, biogenerics in countries such as India and China are already thriving.[10]

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[5] "Key Industry Facts About PhRMA." *PHRMA*. Web. 05 Apr. 2010. <http://www.phrma.org/key_industry_facts_about_phrma>.
[6] Ibid, PhRMA Key Industry Facts.
[7] Dickerson, Wendy. "Biogenerics: The World Is Not Waiting for the U.S. to Decide on Regulations." *Nerac Insights*. Nerac, Research & Advisory Firm. Web. 4 Apr. 2010. <http://www.nerac.com/nerac_insights.php?category=articles&id=75>.
[8] European Union. European Medecines Agency. Committee for Medicinal Products for Human Use. *Guideline on Similar Biological Medicinal Products*. 20 Oct. 2005. Web. <http://www.ema.europa.eu/pdfs/human/biosimilar/043704en.pdf>.
[9] "The European Biosimilars Market: Trends and Key Success Factors." *Scicasts*. 27 Oct. 2008. Web. 4 Apr. 2010. <http://scicasts.com/specialreports/20-biopharmaceuticals/2152-the-european-biosimilars-market-trends-and-key-success-factors/>.
[10] Langer, Eric S. "China Today: Biogenerics in China: An Evolving Industry." *BioPharmInternational.com*. 1 June 2007. Web. 4 Apr. 2010. <http://biopharminternational.findpharma.com/biopharm/Article/China-Today-Biogenerics-in-China-An-Evolving-Indus/ArticleStandard/Article/detail/432388>.

INDUSTRY OUTLOOK

According to IMS Health, a pharmaceutical research firm, short-term sales trends for the pharmaceutical industry expect to increase by 4-6% in 2010. While this increase in sales may seem like a net positive for the industry, compared to 10% yearly growth from 1999-2008, Big Pharma is heading for a slump.[11] We can attribute this downturn to several major causes:

Declining Research and Development

Traditionally, research and development is one of the highest costs for pharmaceutical manufacturers. A commonly accepted estimate is that for every approved new drug, pharmaceutical companies spend $800M on research and development.[12] In fact, only one compound is brought to market for every 5,000 compounds discovered. While these are historical estimates, the pharmaceutical industry has had a major decline in innovation since 2004. From 2004 to 2008, US drug manufacturers increased research and development spending by 30% over the previous period. Yet, this 30% increase in spending has actually led to a 33% drop in the number of approved new molecular entities.[13]

Upcoming Patent Expiration

As a player in the pharmaceutical industry, there is the inherent risk of patent expiration that occurs twenty years after the discovery of a new molecular entity.[14] From 2009 to 2013, the losses to the industry due to patent expiration will be unrivaled. According to IMS Health, the pharmaceutical industry will experience a loss of $137B in sales, roughly 18% of the industry total, from 2009 to 2013. Two major examples include Pfizer who will lose Effexor and Lipitor,

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[11] Ibid, Saftlas Dec 2009.
[12] *A CBO Study: Research and Development in the Pharmaceutical Industry*. Rep. Congressional Budget Office, Oct. 2006. Web. 30 Mar. 2010. <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf>.
[13] Saftlas, Herman. "Industry Survey: Healthcare: Pharmaceuticals." Standard and Poor's, 04 Jun. 2009.
[14] Ibid, PhRMA Key Industry Facts.

which are worth $11.6B in annual sales and Merck who will lose Cozaar and Singulair, which are worth $5.6B in annual sales. Generic companies such as Teva Pharmaceuticals stand to reap the benefits of these patent expirations. Standard & Poor's believes that the impending patent cliff is unprecedented in both total size of revenue lost and total number of drugs going off patent.[15]

The lack of productive pipelines combined with the upcoming patent expirations poses many problems for the pharmaceutical industry. Strategic management and timely decisions will play a vital role in the future of pharmaceutical companies.

INDUSTRY RESPONSE

The impending patent losses in the pharmaceutical industry have prompted many key players to make drastic and strategic decisions. Most of the strategies aim at increasing sales, cutting costs, strengthening research and development, and increasing the quantity and quality of the pipeline.

Mergers and Acquisitions

While some smaller M&A activity occurred, three blockbuster deals happened in 2009. Pfizer acquired Wyeth for $68B, Merck acquired Schering-Plough for $41B, and Roche acquired Genentech for $46B. Each of these acquisitions aimed at increasing sales through diversification in both products and pipelines, and decreasing costs by combining distribution and R&D costs. The Roche acquisition of Genentech was also strategic in that Genentech is a Biotech company, and at least for the time being, approval for generic versions of biologics is extremely challenging due to legal roadblocks.[16]

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[15] Ibid, Saftlas Dec 2009.
[16] Ibid, Saftlas Dec 2009.

Cost-Cutting Programs

Five major pharmaceutical companies have launched cost-cutting initiatives to reduce the strain on their margins. This has entailed cutting sales force employees, consolidating manufacturing facilities and other minor cuts. Pfizer and Merck are running the most extensive cost-cutting programs with goals ranging between $4B and $5.5B in reductions.[17]

COMPANY OVERVIEW: PFIZER INC.

Pfizer Inc. is a global, diversified biopharmaceutical company that discovers, develops and manufactures pharmaceuticals, biologics, nutritional products and consumer products to promote human and animal health.[18] Founded in 1849 by Charles Pfizer and Charles Erhart in Brooklyn, NY and based in New York, New York, Pfizer is the largest pharmaceutical firm in the world (in terms of revenue).[19] Pfizer's revenue grew to over $50B in 2009 and the company employs over 116,000 people worldwide.[20]

Business Segments and Products

Pfizer has two major business segments that function as distinct commercial organizations. The Biopharmaceutical segment accounts for around 91% of total revenues and consists of all of Pfizer's prescribed products. This segment further divides into five business sub-segments in order to promote efficient and focused management. The five sub-segments include Primary Care, Specialty Care, Oncology, Established Products and Emerging Markets.[21] In these five

[17] Ibid, Saftlas Dec 2009.
[18] *Pfizer,Inc*. (2009). 2009 Financial Report. Retrieved from http://media.pfizer.com/files/annualreport/2009/financial/financial2009.pdf.
[19] "Pfizer, Inc Stock Report." *Standard and Poor's*. 3 Apr. 2010. Web. 6 Apr. 2010.
[20] Ibid, 2009 Pfizer Financial Report.
[21] Ibid, 2009 Pfizer Financial Report.

sub-segments, Pfizer markets over 100 different drugs across a diverse array of illnesses.[22] Below is a list of Pfizer's 2009 blockbuster[23] drugs[24]:

Product Name	Purpose	2009 Sales	2009 % of Company Revenue
Lipitor	reduces LDL cholesterol	$11.43B	22.86%
Lyrica	treats epilepsy, fibromyalgia, neuralgia, diabetic neuropathy	$2.84B	5.67%
Celebrix	treats arthritis pain and inflammation	$2.38B	4.76%
Norvasc	treats hypertension	$1.97B	3.94%
Viagra	treats erectile dysfunction	$1.89B	3.78%
Xalatan/Xalacom	treats glaucoma	$1.73B	3.47%
Detrol	treats overactive bladder	$1.15B	2.30%
Zyvox	treats bacterial infections	$1.14B	2.28%
Geodon/Zeldox	treats schizophrenia	$1.00B	2.00%

Pfizer's second major business segment is Diversified products. It acts as the umbrella for all of their non-biopharmaceutical products, which include animal health products, consumer healthcare products, gelatin capsule products and nutrition products. While this segment only accounts for roughly $4.2B, it adds essential diversity to Pfizer's offerings.[25] (For financial details about each business segment see Figure 1).

Research and Development

Of all the firms in Big Pharma, Pfizer has been most reliant on mergers and acquisitions, not research and development, to bolster their pipeline and increase their chances of FDA approval. This becomes extremely apparent when assessing their R&D spending. In 2009, Pfizer spent $7.84B on research development, representing a net 3% decrease in R&D expenditures since

[22] "Pfizer Product List March 2010." *Pfizer, Inc.* Mar. 2010. 4 Apr. 2010.
[23] For this paper, I will define a blockbuster drug as any drug that has net annual sales greater than $1B.
[24] Ibid, 2009 Pfizer Financial Report.
[25] Ibid, 2009 Pfizer Financial Report.

2007.[26] Furthermore, Pfizer's 2009 R&D-to-sales ratio was only 15.68%, relatively low compared to the industry's average of roughly 19%.[27] On a relative basis, Pfizer's R&D productivity has trailed their competitors.[28]

Despite decreased spending on R&D, acquisitions have aided Pfizer in maintaining breadth and depth in their pipeline. They currently have 133 molecules in their pipeline with four potential blockbuster drugs in late-stage development. These potential blockbusters include molecules to treat rheumatoid arthritis, osteoarthritis and small-cell lung cancer. Furthermore, Pfizer has recently prioritized their R&D efforts into six key areas that have high consumer demand for products. These "Invest to Win" areas include Oncology, Pain, Inflammation, Alzheimer's disease, Psychoses and Diabetes.[29]

Mergers and Acquisitions

Since 2000, Pfizer has been involved in three different mega-merger deals, all leading to the creation of the industry's largest company. In 2000, Pfizer merged with Warner-Lambert in a $90B deal.[30] In 2002, Pfizer bought Pharmacia in a $60B deal that gave Pfizer the rights to blockbuster arthritis drug, Celebrex.[31] Finally, in October 2009, Pfizer completed the acquisition

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[26] Ibid, 2009 Pfizer Financial Report.
[27] Ibid, 2009 Pfizer Financial Report; Ibid, CBO Study.
[28] Ibid, Pfizer's S&P Report.
[29] *Pfizer,Inc*. (2009). Annual Review 2009. Retrieved from http://media.pfizer.com/files/annualreport/2009/annual/review2009.pdf.
[30] Pfizer, Inc. *PFIZER AND WARNER-LAMBERT AGREE TO $90 BILLION MERGER CREATING THE WORLD'S FASTEST-GROWING MAJOR PHARMACEUTICAL COMPANY*. *Pfizer Newsroom*. 7 Feb. 2000. Web. 4 Apr. 2010. <http://www.pfizer.ca/english/newsroom/press%20releases/default.asp?s=1&year=2000&releaseID=29>.
[31] Frank, Robert, and Scott Hensley. "Pfizer to Buy Pharmacia For $60 Billion in Stock." *Wall Street Jounral* 15 July 2002. Web. 4 Apr. 2010.

of Wyeth for $68B, which further diversified Pfizer into biologics, including a superb lineup of vaccines.[32]

Pfizer has also been active in acquiring much smaller firms. From 2007 to 2008, they acquired five biotech companies (all valued under $500m) and three animal health companies.[33] These smaller acquisitions often add depth to the early-stages of a pharmaceutical company's pipeline.

Recent Financial Performance

From 2008 to 2009, Pfizer experienced a 3.5% increase in revenues and a 6.5% increase in net income. Revenue increased despite a 9.5% increase in cost of sales and a decline in sales of seven of Pfizer's nine blockbuster drugs.[34]

Pfizer's $68B acquisition of Wyeth ($22.5B in debt) caused a decline in their usually stable financial structure. The company's debt-to-earnings ratio increased from 0.8 to 1.8 due to their debt load increasing from $17.3B to $39.5B.[35] Both Fitch and Moody's dropped their bond rating to AA-minus and A1, respectively.[36] Despite the overall decline in financial structure, Pfizer still has a Current Asset balance of $61.67B and a line of credit up to $8.6B.[37]

COMPANY OUTLOOK: PFIZER INC.

Pfizer, like many of its competitors, faces an uphill battle in the upcoming patent cliff. Although it is the largest company in the pharmaceutical industry, Pfizer will face unparalleled losses. From 2010 to 2013, Pfizer will lose patent rights over Lipitor, Effexor (legacy Wyeth), Zosyn

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[32] Ibid, Pfizer's S&P Report.
[33] Ibid, 2009 Pfizer Annual Review.
[34] Ibid, 2009 Pfizer Financial Report.
[35] Aubin, Dena, and Karen Brettell. "Moody's, Fitch Cut Pfizer's Credit Rating." *Reuters.com*. 15 Oct. 2009. Web. 4 Apr. 2010. <http://www.reuters.com/article/idUSN1531737820091015?loomia_ow=t0:s0:a49:g43:r1:c1.000000:b30471262:z0>.
[36] Ibid, Aubin and Brettell.
[37] Ibid, 2009 Pfizer Financial Report.

(legacy Wyeth), Rapamune (legacy Wyeth), Xalatan and Caduet. These account for what would have been $16.37B in annual revenues.[38]

Despite a strategy based on M&A instead of internal R&D, Pfizer has sales potential in some of its late-stage molecules. S&P analysts believe that by 2014, all of Pfizer's Phase III and later molecules will account for $5.88B in sales.[39] These sales will not make up for all of the firm's losses, but will help soften the blow.

COMPANY STRATEGIC RESPONSE: PFIZER INC.

Pfizer has been extremely proactive in their attempt to counterbalance the upcoming patent cliff. The company's managers have launched strategic initiatives through mergers and acquisitions, cost cutting, research and development restructuring, and legal settlements.

Cost Cutting

Pfizer started a cost cutting initiative in January 2009 with expected cuts to total $3B. Furthermore, after the Wyeth merger, Pfizer expects cost synergies and further cuts to result in a $4B drop in expenses. Of the expected $7B saved, Pfizer will reinvest approximately $2-4B in the business' growth. To achieve these goals, Pfizer has closed down six research and development sites and consolidated four others. They also attacked R&D spending by dropping the total 3% since 2007. Further cost cutting initiatives have resulted in reducing the workforce

[38] "Wyeth's First-quarter 2009 Profit Flat Year-on-year as It Prepares for Pfizer Mega-merger." *The Pharma Letter*. 29 Apr. 2009. Web. 19 Apr. 2010. <http://www.thepharmaletter.com/file/ffd08fd2c55a4d051ece94904922c885/wyeths-first-quarter-2009-profit-flat-year-on-year-as-it-prepares-for-pfizer-mega-merger.html>.; Ibid, 2009 Pfizer Financial Report.; Ibid, Saftlas Dec 2009.

[39] Ibid, Saftlas Dec 2009.

across all business segments from 120,700 employees to 116,500 employees and potential closure of several of Pfizer's 81 manufacturing sites.[40]

Mega-Merger with Wyeth

In addition to the cost savings detailed above, the merger with Wyeth provided additional benefits to counteract the patent cliff that Pfizer faces. Adding Wyeth has greatly increased Pfizer's presence in the generic-free biologics arena, especially in vaccines. Wyeth's vaccine product line includes Prevnar vaccine for childhood infections and Enbrel, which treats rheumatoid arthritis. Furthermore, the acquisition of Wyeth's consumer products department will allow Pfizer to diversify back into non-prescription products, after they sold off their consumer product segment to Johnson & Johnson over two years ago.[41]

Acquisitions to Diversify

Over the past two years, Pfizer has been extremely active in acquiring small biotech and animal health firms to help diversify and add depth to their R&D pipeline. While this is likely a play for the long term, it shows that Pfizer is attempting to place less of its revenue stream on products with patent expirations.

R&D Focus

Although Pfizer has strategically opted for acquisitions over organic growth, they have still implemented a plan to optimize their pipeline. Titled the "Invest to Win" plan, they have focused their efforts on late-stage molecules to treat Oncology, Pain, Inflammation, Alzheimer's disease, Psychoses and Diabetes, as well as biologics and vaccines. All of these categories have high

[40] Ibid, 2009 Pfizer Annual Review.

[41] Hall, Jessica, and Lewis Kraukopf. "Pfizer to Buy Wyeth for $68 Billion." *Reuters.com*. 26 Jan. 2009. Web. 4 Apr. 2010. <http://www.reuters.com/article/idUSTRE50M1AQ20090126?feedType=nl&feedName=ustopnewsearly>.

demand and thus are ripe for blockbuster drugs to recover lost revenues. The plan has been a success with 75% of late-stage molecules focused in those areas.[42]

Expansion into China

In an attempt to increase sales in a growing market, Pfizer has made some impressive moves into China's pharmaceutical market. First, Pfizer has formed a partnership with Japanese pharmaceutical firm Takeda to promote the Type 2 Diabetes drug Actos in China. Furthermore, Pfizer has plans to work with Crown Bioscience to develop treatments for cancer types that are common in East Asia.[43]

Further Grow Generic Business

Pfizer launched their Established Products business segment in 2008 under the subsidiary Greenstone LLC. Through licensing agreements and sales of off-patent Pfizer drugs, Greenstone now accounts for 14% of Pfizer's total revenues. This figure is set to grow with the patent losses that Pfizer faces in the coming years.[44]

Ranbaxy Deal with Lipitor Patent Rights

Most pharmaceutical companies have powerful legal departments that attempt to fight off generic company's bids for patent information. Pfizer was in a losing position in a legal battle with Ranbaxy Labs Ltd. regarding the patents they held over Lipitor. Instead of turning over the intellectual property, Pfizer was able to strike a deal in which they would retain protection until

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[42] Ibid, 2009 Pfizer Annual Review.
[43] Harris, Frederick L. *Pfizer Inc*. Publication. Valueline, 2010. *Valueline*. Web. 4 Apr. 2010.
[44] Pfizer, Inc. Greenstone LLC. *PFIZER EXPANDS PORTFOLIO OF GENERIC MEDICINES IN THE U.S. AND EUROPE THROUGH LICENSING AGREEMENTS WITH AUROBINDO*. 3 Mar. 2009. Web. 4 Apr. 2010. <https://www.greenstonellc.com/greenstone/html/greenstone/pressreleases.htm>.

November 2011 at which point they would allow Ranbaxy to produce the generic version. This deal afforded Pfizer an extra 20 months of patented production for Lipitor, worth over $12B.[45]

RECOMMENDATIONS FOR PFIZER INC.

Short Term (Commence within 1 year)

Generic Versions of Blockbuster Drugs

Pfizer's generic products, produced under the guise of business segment Established Products and subsidiary Greenstone LLC, grew 23% from 2007 to 2009.[46] Furthermore, it grew from under 13% of Pfizer's total revenue, to well over 15%.[47] Undoubtedly, Pfizer views this section of their business as a necessity for diversification, despite the relatively small margins.[48] In order to use this subsidiary to its maximum potential, Pfizer should strategically launch generic versions of the blockbuster drugs as they go off patent. If they release the generic version several weeks before patent expiration, Pfizer will gain a first mover advantage into the market for that specific generic drug. In a market where Lipitor is worth $11.4B, this could prove to be a sizable share of revenue.

Increase Research & Development via Outsourcing

Pfizer has experienced a decline in R&D spending of 3% since 2007.[49] As a percentage of total revenue, R&D spending has dropped from 16.7% to 15.7% over that same period.[50] Understanding that one of the key forces behind the upcoming patent cliff is the lack of innovation from Big Pharma, it comes as a surprise that Pfizer would be as bold as to lower their

[45] Decker, Susan, and Shannon Pettypiece. "Pfizer, Ranbaxy Delay Generic Lipitor for 20 Months." *Bloomberg.com*. 18 June 2008. 4 Apr. 2010. <http://www.bloomberg.com/apps/news?pid=20601087&sid=aXsUuNFIiswQ>.
[46] Ibid, 2009 Pfizer Financial Report.
[47] Ibid, 2009 Pfizer Financial Report.
[48] Goldstein, Jacob. "Pfizer Goes Generic." Web log post. *WSJ Health Blogs*. 16 Oct. 2008. Web. <http://blogs.wsj.com/health/2008/10/16/pfizer-goes-generic/tab/article/>.
[49] Ibid, 2009 Pfizer Financial Report.
[50] Ibid, 2009 Pfizer Financial Report.

expenditures on R&D and close down R&D facilities. Since Pfizer's overall strategy aims at inorganic growth, I recommend that they increase their R&D expenditures on outsourced contract research organizations (CROs). Firms such as Quintiles Transnational Corp., Pharmaceutical Product Development Inc., and Covance Inc. can provide less expensive and more efficient R&D staffing.[51] The cost savings is readily apparent because of their lower overhead costs resulting from facilities in Eastern Europe, China and India.[52] This move towards inorganic R&D fits well with Pfizer's current strategy, reduces overall costs and aids in innovation.

Long Term (Commence within 3 years)

Further Diversification into Generics and Consumer Products

As previously stated, Pfizer's generics business has grown rapidly since 2007. Furthermore, Pfizer's acquisition of Wyeth has allowed them to reenter the consumer healthcare market with powerful brands such as Advil, Centrum, ChapStick, Robitusson and Preparation H. Although neither product category offers margins as high as traditional pharmaceutical products, generics and consumer products offers a stream of revenue that is not subject to patent removal. In order to diversify into these markets, Pfizer should aim to acquire already existing businesses. After Teva Pharmaceuticals beat out Pfizer in a bidding war for German-based generic company Ratiopharm, Pfizer should refocus on existing targets.[53] One potential takeover target is STADA Arzneimittel. STADA has a large presence in the German generic drug market, which is the

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[51] Saftlas, Herman. "Industry Survey: Healthcare: Pharmaceuticals." Standard and Poor's, 27 Nov. 2008.
[52] Ibid, Saftlas Nov 2008.
[53] Kirchfeld, Aaron, and Naomi Kresge. "Teva Beats Pfizer to Win Ratiopharm for $5 Billion." *BusinessWeek*. 18 Mar. 2010. Web. 4 Apr. 2010. <http://www.businessweek.com/news/2010-03-18/teva-said-to-beat-pfizer-actavis-to-win-ratiopharm-update1-.html>.

second largest in the world behind the United States.[54] In addition, their business model focuses solely on generic drugs and branded healthcare products and they have a presence in 28 international markets focused mainly in Europe and Asia.[55]

Reduce Reliance on Blockbuster Drugs through International Partnerships

In most industries, a top-selling, high margin product is ideal. While this is sought after in the pharmaceutical industry, patent expirations change the overall goal. Pharmaceutical companies need top-selling, high margin products that are a relatively small percent of revenues. One of the reasons behind Pfizer's patent cliff is the company's dependence on Lipitor. With over 22% of company revenues coming from Lipitor, patent expiration poses a significant problem.[56] Diversification and growth of the business will help lower dependency on any single product, but in order to ensure lower dependency, Pfizer should engage in more R&D partnerships. By collaborating with international companies, such as Takeda, Novartis or Daiichi Sankyo, Pfizer can cut costs on R&D, distribution and marketing, while ensuring that they each inherit the revenues of different international markets. Purposefully sharing revenues may seem illogical, but it cuts costs and ensures lower reliance on the drug's revenues. This will strengthen the business' outlook because patent loss will no longer result in a 20% or more drop in revenues.

Increase Presence in "Pharmerging Markets"

Known in the pharmaceutical arena as the Pharmerging Markets, India, China, Russia, Brazil, Mexico, South Korea and Turkey will make up over 30% of world sales growth in the

[54] Ibid, Kirchfeld and Kresge.
[55] "Company Profile: The Strategy." *STADA Arzneimittel AG*. Web. 19 Apr. 2010. <http://www.stada.de/english/about/profile/strategy.asp>.
[56] Ibid, 2009 Pfizer Financial Report.

pharmaceutical market through 2013.[57] Pfizer's 2009 revenues in emerging markets represented just under 13% of total revenues.[58] While this clearly proves that Pfizer has begun to access these markets, it is important that they increase their presence by collaborating with firms who fully understand the market needs and cultural differences. It is important that Pfizer strengthen their relationship with Japanese pharmaceutical firm Takeda in order to access East Asian markets and the Mexican market (Takeda just built a subsidiary there).[59] In addition, partnerships with Indian generic firms Ranbaxy Laboratories or Dr. Reddy's Pharmaceutical Company would certainly provide mutual benefits to both companies.

COMPANY OVERVIEW: ELI LILLY AND COMPANY

Eli Lilly is a pharmaceutical company that discovers, develops, manufactures and sells pharmaceutical products. Founded in 1876 as a small business in Indianapolis, Indiana, Lilly now employs over 40,000 employees worldwide and had revenues upwards of $21B in 2009. With research and development firms in eight countries, manufacturing plants in thirteen countries and marketed products in 143 countries, Lilly is truly a global corporation.[60]

Business Segments and Products

After undergoing a major restructuring effort in 2009, Lilly operates in two major business segments. The first is their Core Pharmaceutical segment that focuses on pharmaceutical products for humans. This business segment is further broken down into four sub-segments: Lilly Bio-Medicines, Oncology, Diabetes, and Emerging Markets. Lilly's Core Pharmaceutical

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[57] Eli Lilly and Company. *Lilly Outlines Innovation Strategy, Reviews Promising Pipeline of Potential Medicines and Sets 2010 Financial Guidance*. *Lilly.com*. 10 Dec. 2009. Web. 3 Apr. 2010. <http://newsroom.lilly.com/releasedetail.cfm?releaseid=429287>.

[58] Ibid, 2009 Pfizer Financial Report.

[59] "The Pharmaceutical Market: Mexico." *Espicom: Business Intelligence*. 27 Jan. 2010. Web. 4 Apr. 2010. <https://www.espicom.com/Prodcat.nsf/Search/00000356?OpenDocument>.

[60] *Eli Lilly and Company*. Web. 04 Apr. 2010. <http://lilly.com>.

segment has a portfolio of 22-patented products to treat a range of diseases. Details of the best selling products (in terms of revenue) are below (See Figures 2 and 3 for more details)[61]:

Product Name	Purpose	2009 Sales	2009 % of Company Revenue
Zyprexa	treats schizophrenia, bipolar disorder and bipolar maintenance	$4.92B	22.53%
Cymbalta	treats major depressive disorder, anxiety disorder	$3.07B	14.06%
Humalog	treats diabetes	$1.96B	8.98%
Alimta	treats several types of lung cancers	$1.71B	7.83%
Cialis	treats erectile dysfunction	$1.56B	7.14%
Gemzar	treats several types of cancer including breast, pancreatic, lung, ovarian and bladder	$1.36B	6.23%
Evista	treats osteoporosis	$1.03B	4.72%
Humulin	treats diabetes	$1.02B	4.67%

Lilly's second business segment focuses on Animal Health products and operates under the name Elanco.[62] Elanco develops Animal Health products for protein production, companion animal health and food safety. Elanco sells the majority of these products to the food industry "to produce an abundant supply of safe nutritious and affordable food."[63] Animal Health products account for roughly 5.5% of total sales.[64]

Marketing – Promotion and Distribution

Lilly's marketing efforts differ based on the country of operation. In the United States, Lilly promotes its products by using sales representatives who talk to medical professionals and print ads, websites and TV commercials aimed at the end consumer. Outside of the United States,

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[61] *Eli Lilly and Company*. (2009). 2009 Annual Report. Retrieved from http://investor.lilly.com/common/download/sec.cfm?companyid=LLY&fid=950123-10-14958&CIK=59478.
[62] Ibid, 2009 Lilly Annual Report.
[63] *Animal Health, Elanco.com*. Web. 04 Apr. 2010. <http://elanco.com>.
[64] Ibid, 2009 Lilly Annual Report.

promotional efforts are dominated by the use of sales representatives who target medical professionals.[65]

Lilly also handles distribution differently in the United States than it does in the international market. Distribution can be a high cost for pharmaceutical manufacturers, so it is extremely important to insure efficiency and low cost. In the United States, Lilly distributes its products through independent wholesale distributors. The three largest, AmerisourceBergen, McKesson and Cardinal Health, account for upwards of 30% of net sales. Outside the United States, the type of distribution changes based on the country's infrastructure, but it is usually maintained by a Lilly sales organization or marketed through an independent distributor.[66]

Research and Development

With one of the highest R&D-to-sales ratios in the pharmaceutical industry at 19.8%, Lilly has shown their dedication to the development of future products via their pipeline. Currently, Lilly has 64 molecules in development, of which 29 are in Phase II or III of approval with the U.S. Food and Drug Administration (See Figure 4). Furthermore, two of the molecules in Phase III are for the treatment of Alzheimer's disease, a market in which there is tremendous demand for pharmaceutical products.[67]

Mergers and Acquisitions

Lilly, like many members of Big Pharma, makes acquisitions of pharmaceutical and biotech firms in order to increase their ability to produce the next blockbuster product. In 2008, Lilly acquired biotech firm ImClone for $6.5B and SGX Pharmaceuticals for $64M. Both acquisitions

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[65] Ibid, 2009 Lilly Annual Report.
[66] Ibid, 2009 Lilly Annual Report.
[67] "Eli Lilly and Co Stock Report." *Standard and Poor's*. 6 Mar. 2010. Web. 31 Mar. 2010.

aimed at improving Lilly's oncology pipeline and drug discovery technology.[68] Lilly was also active in 2007, acquiring ICOS Corporation for $2.3B, and Hypnion, Inc. and Ivy Animal Health for a total cost of $445M. The purchase of ICOS gave Lilly the full rights to blockbuster drug Cialis, while Hypnion provided a pipeline of molecules focused on sleep disorders and Ivy Animal Health provided more products for Lilly's Elanco to market.[69]

Recent Financial Performance

Lilly continues to grow as a major competitor in the pharmaceutical market. In 2009, they posted a 7% increase to $21.84B in worldwide revenue following a 9% increase in global sales in 2008. These increases resulted from increased demand and higher prices for many of Lilly's blockbuster drugs. In tandem with increasing revenues, Lilly's gross margin continues to increase from 78.5% in 2008 to 80.6% in 2009. Coming off a net loss in 2008 due to the acquisition of ImClone and a settlement regarding Zyprexa, Lilly was able to rebound with a net income of $229.5M.

Lilly's debt ratings have held solid at AA from S&P and A1 from Moody's and reflect the $3.80B pay-down of commercial paper over the last fiscal year. Lilly still has significant long-term debt due to borrowing made for acquisitions, but their access to the credit markets is still strong due to their commitment to make timely payments and their sound financial structuring. Additionally, Lilly still has $1.24B in unused committed bank credit.[70]

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[68] Ibid, 2009 Lilly Annual Report.

[69] *Eli Lilly and Company*. (2008). 2008 Annual Report. Retrieved from http://investor.lilly.com/common/download/download.cfm?companyid=LLY&fileid=296463&filekey=611E167A-61C9-4C03-8866-ACF5FA7C8953&filename=English.PDF.

[70] Ibid, 2009 Lilly Annual Report.

COMPANY OUTLOOK: ELI LILLY AND COMPANY

Eli Lilly's outlook is in line with the pharmaceutical industry. Lilly will face the loss of four of its top earning products by 2013 (See Figure 3). Zyprexa, Lilly's top earning product, will lose patent in 2011, while Gemzar and Cymbalta expire in 2013. Humalog's patent loss is less detrimental because it is a biologic for which the US does not allow generic competition.[71] This loss amounts to 42.82% of Lilly's sales (in 2009).[72]

To compound the issue of patent losses, it is unlikely that Lilly's pipeline will produce the sales necessary to make up for this loss by 2013. While Lilly's pipeline is strong, many of its potential blockbuster drugs would not be ready for approval until after the slew of patent expirations.

On a positive note, analysts believe that one of Lilly's drugs that just received FDA approval, Effient, could be a blockbuster drug in a market that brings in roughly $8B in annual sales. Diabetes drug, Byetta, which is close to approval, could add several hundred million dollars to Lilly's sales. Furthermore, Lilly does have two promising Alzheimer molecules and several cancer fighting biologic molecules that they acquired from ImClone.[73]

COMPANY STRATEGIC RESPONSE: ELI LILLY AND COMPANY

In Eli Lilly's 2009 Annual Report, the firm highlights that they will not embark on the same path as other firms in the industry. Lilly firmly states that they will not seek to "lower risk by reducing their focus on innovative medicines." Instead, Lilly will look to "create value by accelerating the flow of innovative new medicines that provide improved outcomes for

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[71] Wall, J.K. "Lilly Asks Shareholders to Lower Takeover Barrier." *IBJ.com*. Indiana Business Journal, 20 Feb. 2010. Web. 29 Mar. 2010. <http://www.ibj.com/lilly-asks-shareholders-to-lower-takeover-barrier/PARAMS/article/18213>.

[72] Ibid, 2009 Lilly Annual Report.

[73] Conover, Damien, and Alex Morozov. *Morningstar Equity Research: Eli Lilly & Company*. Rep. *Morningstar*. Web. 31 Dec. 2009.

individual patients." In order to accomplish this feat and fight off the upcoming patent cliff, Lilly has launched several initiatives.[74]

Business Restructuring Program

Until 2009, Lilly operated in two distinct business segments. This resulted in an extremely large and inefficient operation for Human Health and a much smaller, efficient segment for Animal Health.[75] Understanding that large, unfocused business segments breed inefficiencies and unnecessary costs, Lilly embarked on a company-wide reorganization. The main goal of this shift was to "create a clear line of sight from innovation to the customer." The restructuring effort resulted in five key business segments (Bio-Medicines, Oncology, Diabetes, Emerging Markets and Animal Health) that will enable Lilly to utilize its resources efficiently and create innovative products that will benefit consumers and fill their shifting needs.[76]

R&D Restructuring and Increased Spending on Organic Growth

Since 2007, Lilly has increased their research and development expenditures by over 24% to $4.3B in 2009. This growth in spending coupled with the highest R&D-to-sales ratio in the industry proves that Lilly is committed to the organic growth and innovation that they preach.[77]

In addition to the increased spending, Lilly has begun to reshape their R&D department. Instead of operating as a "fully integrated pharmaceutical company," Lilly will operate as a "fully integrated pharmaceutical network" also known as FIPNet. The idea that underlies this new definition is that Lilly will now welcome compounds in areas of interest (such as Alzheimer's disease) from outside sources. In exchange for testing the validity and use of the product, Lilly

[74] Ibid, 2009 Lilly Annual Report.
[75] Ibid, 2008 Lilly Annual Report.
[76] Ibid, 2008 Lilly Annual Report.
[77] Ibid, 2009 Lilly Annual Report.

receives first rights to negotiate a purchase of the compound. This can significantly reduce the cost of discovery. [78]

Lilly has also made investments in other aspects of R&D. These include the creation of a virtual development team that can gain proof of concept (evidence that a drug can be effective in humans) 12 months faster and at half the price of traditional methods and the creation of the Development Center of Excellence which will aim to increase efficiency in drug development.[79]

Setting a New Direction – Move into Biotech

In order to offset the upcoming loss in revenues, Lilly has made it a priority to move into the biologics market. Currently, 24 of Lilly's 64 pipeline molecules are biologics. To continue this trend, Lilly just opened two biotech development centers in Indianapolis and San Diego and is constructing a new biotech manufacturing facility in Ireland to be ready for operation in 2011. In addition to the organic growth of the business, Lilly has also made acquisitions of the following biotech firms: Imclone, SGX Pharmaceuticals, ICOS Corporation and Hypnion.[80]

Partnerships

Another tactic that Lilly will use to secure their future finances is to form partnerships with other pharmaceutical and biotech firms. Partnerships may reduce overall revenues, but they are very helpful in tough economic climates since they help cut costs and risk involved with a specific project. Over the past year, Lilly has signed an agreement with Kowa Pharmaceuticals to

[78] Ibid, 2009 Lilly Annual Report.
[79] Ibid, 2009 Lilly Annual Report.
[80] Ibid, 2009 Lilly Annual Report.

promote a cholesterol-lowing drug and with Incyte Corporation to promote a rheumatoid arthritis treatment. [81]

Cost Reduction Efforts

Like many pharmaceutical firms, Lilly has embarked on a companywide cost cutting initiative. In 2008, Lilly sold off their Greenfield Laboratories R&D site and in 2010 they sold off one of their manufacturing sites. In addition, Lilly has reduced their overall headcount by 5,000 employees and have saved over $1B since launching a Six Sigma program more than five years ago. These cost-cutting initiatives are an attempt to lower their cost base in anticipation of their upcoming loss of revenue. So far, the cost-cutting initiative has worked, increasing revenue-per-employee by 75% since 2004.[82]

RECOMMENDATIONS FOR ELI LILLY AND COMPANY

Short Term (Commence within 1 year)

Increase R&D Expenditures

Lilly is committed to innovation and developing a pipeline of quality molecules. Over 2009, Lilly backed up this commitment with expenditures of roughly $4.3B on research and development that accounted for 19.8% of their total sales.[83] In order for Lilly to stay competitive and survive the impending patent drop off, I recommend that they increase R&D expenditures. With nearly $12.5B in current assets and a healthy balance sheet, I recommend that Lilly devote $6B to R&D in 2010 and continue to grow this number by 15% until the patent expirations begin.

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[81] Ibid, 2009 Lilly Annual Report.
[82] Ibid, 2009 Lilly Annual Report.
[83] Ibid, 2009 Lilly Annual Report.

Focus R&D on Late-Stage & Biotech Molecules

In addition to increasing funds for R&D, Lilly should focus their R&D expenditures on late-stage molecules and biologic molecules. Expenditures on these specific pipeline groups will best prepare Lilly for the impending patent-cliff. While Phase I molecules represent the long-term future of Lilly's portfolio, it is important that Lilly divert a majority of funds to develop molecules in Phase II or Phase III of FDA approval. Phase II and III molecules represent Lilly's best chance for short-term revenue streams. Beside for focusing funds on late-stage molecules, I recommend that Lilly focus funding into biologic molecules. At present, products developed in the biologics arena are not susceptible to generic competition.

Acquisition of Small Biologics Firm

Lilly has made a company stance that they will not engage in a mega-merger like Pfizer and Wyeth or Merck and Schering-Plough, citing that the benefit for shareholders does not exist.[84] However, the takeover of a smaller biotech firm would help solve both short-term and long-term problems. Although Lilly purchased ImClone in 2008, their Balance Sheet remains strong (making debt a viable option) and they have nearly $4.5B in cash and cash equivalents.[85] An ideal target would have one or two current biologics and a late-stage pipeline of promising biologic molecules. Furthermore, the takeover target should have a market cap under $5B and minimal debt so that Lilly's financial situation can remain healthy. Possible candidates include Amylin Pharmaceuticals and Alexion Pharmaceuticals. Amylin proves as an interesting target because they have two products on market to treat diabetes and a solid late-stage pipeline with a

[84] Ibid, 2009 Lilly Annual Report.
[85] Ibid, 2009 Lilly Annual Report.

focus in diabetes and obesity.[86] Furthermore, Lilly knows their business structure well because of a current partnership they have marketing exenatide (Byetta).[87] Alexion is a slightly larger organization, but its products and pipeline would help diversify Lilly.[88] Alexion's product and pipeline focus high need products for hematologic, kidney and neurological diseases, transplant rejection, cancer and autoimmune diseases.[89]

More Cost-Cutting: Marketing and Sales

Lilly has made efforts to reduce costs by reducing excess manufacturing capacity, consolidating R&D facilities, implementing a massive restructuring effort and reducing total headcount by 5,000 employees.[90] While cost cutting efforts are expected to reduce the overall cost base by $1B by 2011, it is important that efforts continue.[91] I recommend that Lilly make the largest cuts to the company's marketing and sales expenditures. This would involve reducing the sales force, cutting back on physician marketing and cutting back on direct to consumer advertising.

Long Term (Commence within 3 years)

Partner, Acquire or Merge with a Generic Drug Manufacturer

Several Big Pharma firms have already invested (mostly through acquisition) in the generic markets. Novartis and GlaxoSmithKline are just two examples, buying up Sandoz and Aspen to diversify into the generic markets.[92] In order to stop patent expirations from continuing to be the Achilles heel of Eli Lilly, Lilly must form a relationship, whether it is through partnership,

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[86] "Profile: Amylin Pharmaceuticals, Inc." *Reuters*. Web. 02 Apr. 2010. <http://www.reuters.com/finance/stocks/companyProfile?rpc=66&symbol=AMLN.O>.
[87] Ibid, Amylin.
[88] *Alexion Pharmaceuticals*. Web. 02 Apr. 2010. <http://www.alxn.com/>.
[89] Ibid, Alexion.
[90] Ibid, 2009 Lilly Annual Report.
[91] Ibid, 2009 Lilly Annual Report.
[92] "Big Pharma Looks to Generics and Biotech for Growth." *Managing Intellectual Property*. Web. 05 Apr. 2010. <http://www.managingip.com/Article/2004484/Big-pharma-looks-to-generics-and-biotech-for-growth.html>.

acquisition or merger, with a generic drug producer. This type of relationship with a generics firm would allow Lilly to recoup some of the losses that ordinarily come paired with a patent loss of a branded drug. The most likely takeover candidate is Mylan Inc because they are a relatively small company (Market Cap of $7B) compared to their competitors and they have a presence in 140 countries.[93] The most likely partnership or merger would be with Israeli generic company Teva Pharmaceuticals. A much larger company than Mylan, there are estimates that Teva owns upwards of 22% of the US generic market[94]

Increase Sales Efforts in "Pharmerging" Markets

Similar to my recommendations for Pfizer, it is important that Eli Lilly increase its presence in emerging markets (India, China, Russia, Brazil, Mexico, South Korea and Turkey). In 2009, these markets only made up 9% of Lilly's sales.[95] I recommend that Lilly focus on developing an improved sales network in these emerging markets without drastically increasing the company's fixed assets. In order to accomplish this goal, I recommend that Lilly form partnerships with local pharmaceutical companies, manufacturers and distributors in order to penetrate the markets. This would keep costs down but also drive sales growth.

More Acquisitions of Small Biologics Firms

First mentioned in short-term goals, I will reiterate that Lilly must continue to seek out small Biotech firms for acquisition. In the long-term, the target firms no longer need to have

[93] Orelli, Brian. "The Next Pharma Acquisition." *The Motley Fool*. 07 Aug. 2008. Web. 03 Apr. 2010. <http://www.fool.com/investing/high-growth/2008/08/07/the-next-pharma-acquisition.aspx>.

[94] Kimes, Mina. "Generic-drug Maker Teva Steals Market Share from Big Pharma - Aug. 5, 2009." *CNNMoney: Fortune*. 05 Aug. 2009. Web. 03 Apr. 2010. <http://money.cnn.com/2009/08/04/news/companies/generic_drugs_pharmaceutical.fortune/index.htm>.

[95] Ibid, Lilly Innovation Strategy.

marketable products, but instead must have expansive pipelines. By acquiring new biotech firms, Lilly will ensure a stable pipeline of molecules that will never experience generic competition.

CONCLUSIONS

Pfizer and Eli Lilly both face precipitous losses in the upcoming years. While some strategies overlap, Pfizer's push for inorganic growth and Lilly's focus on innovation and organic growth are inherently different. Although it is hard to conclude which company will have more success both short and long term, my analysis leads me to several conclusions.

Pfizer's current strategies, including the mega-merger with Wyeth, leaves Pfizer in a much better position to boost its short-term revenues to offset the impending patent cliff. However, the long-term implications of increasing revenues via acquisition and reducing investment in research and development are extremely dangerous. One of the most important functions and growth factors in the pharmaceutical industry is the ability to create new and innovative products. By only growing the company through acquisition, Pfizer has lost focus on their historical core strength of new molecule research and development.

Lilly's position and focus on internal innovation fueled by increased efficiency in research and development is optimal for a long-term outlook, but will not help the company recover over 42% of their revenues by 2013. Cost reduction efforts and restructuring of Lilly's business segments in tandem with R&D focus on late-stage biologics will bring some immediate cost savings and increased revenues, but this patent cliff will prove hard on Lilly's bottom line. Despite this short-term outlook, Lilly is taking important steps to solidify the future of the company. Focus on internal growth of an innovative pipeline will decrease the likelihood of future patent cliffs and bring long-term revenue and profits.

From my analysis and recommendations, it has become apparent that Pfizer is more prepared to weather the short-term patent cliff than Eli Lilly. Despite this short-term analysis, Lilly's current planning efforts coupled with my strategic recommendations position the company for long-term growth, stability and a decreased risk of a future patent cliff.

APPENDICES

Figure 1: Pfizer's 2009 Revenue by Segment[96]

Revenues by Segment[(a)]
Worldwide revenues follow:

	YEAR ENDED DECEMBER 31,			% CHANGE	
(MILLIONS OF DOLLARS)	**2009**	2008	2007	**09/08**	08/07
Biopharmaceutical:					
Primary Care	**$22,489**	$22,974	$25,700	**(2)**	(11)
Specialty Care	**7,386**	5,971	5,211	**24**	15
Oncology	**1,501**	1,579	1,760	**(5)**	(10)
Established Products	**7,616**	7,462	6,179	**2**	21
Emerging Markets	**6,456**	6,405	5,574	**1**	15
Returns adjustment	**—**	(217)	—	*	*
Total Biopharmaceutical	**45,448**	44,174	44,424	**3**	(1)
Diversified:					
Animal health products	**2,764**	2,825	2,639	**(2)**	7
Consumer healthcare products	**494**	—	—	*	*
Capsugel	**740**	767	685	**(4)**	12
Nutrition products	**191**	—	—	*	*
Total Diversified	**4,189**	3,592	3,324	**17**	8
Corporate/Other[(b)]	**372**	530	670	**(30)**	(21)
Total Revenues	**$50,009**	$48,296	$48,418	**4**	—

(a) Reflects revenues from legacy Wyeth products commencing on the Wyeth acquisition date, October 15, 2009, in accordance with Pfizer's domestic and international year-ends. Prior-period amounts for Capsugel, which previously were classified as *Corporate/Other*, now are included in *Diversified*.
(b) Includes Pfizer Centersource, which includes contract manufacturing and bulk pharmaceutical chemical sales. Also includes transition activity associated with our former consumer healthcare business (sold in December 2006).
* Calculation not meaningful.

96 Ibid, 2009 Pfizer Financial Report.

Figure 2: Eli Lilly's 2009 Product Revenues[97]

Product	Year Ended December 31, 2009 U.S.[1]	Year Ended December 31, 2009 Outside U.S.	Year Ended December 31, 2009 Total[3]	Year Ended December 31, 2008 Total	Percent Change from 2008
	(Dollars in millions)				
Zyprexa	$ 2,331.7	$2,583.9	$ 4,915.7	$ 4,696.1	5
Cymbalta	2,551.8	523.0	3,074.7	2,697.1	14
Humalog	1,208.4	750.6	1,959.0	1,735.8	13
Alimta	815.6	890.4	1,706.0	1,154.7	48
Cialis	623.3	935.8	1,559.1	1,444.5	8
Gemzar	747.4	615.8	1,363.2	1,719.8	(21)
Animal health products	672.2	535.0	1,207.2	1,093.3	10
Evista	682.2	348.1	1,030.4	1,075.6	(4)
Humulin	402.4	619.6	1,022.0	1,063.2	(4)
Forteo	518.3	298.4	816.7	778.7	5
Strattera	445.6	163.7	609.4	579.5	5
Other pharmaceutical products	739.9	1,168.4	1,908.1	1,887.5	1
Total net product sales	11,738.8	9,432.7	21,171.5	19,925.8	6
Collaboration and other revenue[2]	555.6	108.9	664.5	446.1	49
Total revenue	$12,294.4	$9,541.6	$21,836.0	$20,371.9	7

[1]U.S. revenue includes revenue in Puerto Rico.
[2]Collaboration and other revenue is primarily composed of Erbitux royalties and 50 percent of Byetta's gross margin in the U.S.
[3]Numbers may not add due to rounding.

[97] Ibid, 2009 Lilly Annual Report.

Figure 3: Relevant Patent Information for Eli Lilly's Products[98]

Product	Worldwide Revenues (2009)	Percent of Total 2009 Revenues	Relevant U.S. Patent Protection
Zyprexa	$4.92 billion	23	2011
Cymbalta	$3.07 billion	14	2013
Humalog	$1.96 billion	9	2013
Alimta	$1.71 billion	8	2016
Cialis	$1.56 billion	7	2017
Gemzar	$1.36 billion	6	2010 (compound); 2013 (use)[1]
Evista	$1.03 billion	5	2014 (use); 2017 (dosage form)[1]
Strattera	$609.4 million	3	2016

[1]The Gemzar use patent and Evista dosage form patent have been held invalid by federal district courts, and we have appealed those decisions. For more information, see Item 7, "Management's Discussion and Analysis—Legal and Regulatory Matters."

[98] Ibid, 2009 Lilly Annual Report.

Figure 4: Eli Lilly's Product Pipeline[99]

Phase 1			Phase 2		Phase 3	Regulatory Review/ Prelaunch
cancer	Gemcitabine prodrug cancer	diabetes	Eg5 inhibitor cancer	iGluR5 antagonist pain	Enzastaurin diffuse large B-cell lymphoma	Arxxant diabetic retinopathy
alcohol dependence	TGF β inhibitor cancer	diabetes	LY2599506 diabetes	LY2624803 insomnia	GLP-1 Fc diabetes	Livalo lipidemia
alcohol dependence	IMC-18F1 cancer	Basal insulin diabetes	IL-23 antibody psoriasis	mGlu2/3 pro II schizophrenia	IMC-11F8 non-small cell lung cancer	
atherosclerosis	IMC-EB10 cancer	migraine prevention	agitation in Alzheimer's	NERI depression	IMC-1121B breast/gastric cancers	
atherosclerosis	cancer	obesity	cancer	OpRA alcohol dependence	Semagacestat Alzheimer's	
benign prostatic hyperplasia	cancer	obesity	IMC-3G3 cancer	obesity	Solanezumab Alzheimer's	
bone healing	eIF-4E ASO cancer	osteoarthritis	IMC-A12 cancer	INCB28050 rheumatoid arthritis	Teplizumab diabetes	
cancer	TGF β antibody chronic renal disease, cancer	osteoporosis	CD20 antibody non-Hodgkin's lymphoma	IL-17 antibody rheumatoid arthritis	Tasisulam melanoma	
cancer	depression	pain	diabetes	BAFF antibody rheumatoid arthritis		
cancer	diabetes	schizophrenia	GLP-1 PEG diabetes	Survivin ASO prostate cancer		
cancer	diabetes	uterine fibroids	IL-1 β antibody diabetes			

Phase 1 Phase 2 Phase 3 Regulatory Review/ Prelaunch

New Chemical Entity

New Biotech Entity

[99] Ibid, 2009 Lilly Annual Report.