



Eli Lilly and Company  
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Indianapolis, Indiana 46285  
U.S.A.

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**VIA EDGAR**

**August 27, 2010**

Mr. Jim B. Rosenberg  
Senior Assistant Chief Accountant  
Division of Corporate Finance  
U.S. Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549

Re: Eli Lilly and Company  
Form 10-K for the Fiscal Year Ended December 31, 2009  
File Number 001-06351

Dear Mr. Rosenberg:

Eli Lilly and Company (Lilly) submits this response to your letter dated July 27, 2010 commenting on our Form 10-K for the year ended December 31, 2009, our DEF 14A filed March 8, 2010, and our Form 10-Q for the quarter ended March 31, 2010. For ease of reference we have repeated your comments prior to our responses.

**Comment:**

**Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition**  
**Executive Overview, page 18**

1. Please refer to your response to comment one. Please provide us with the revised disclosure that you propose to include in future filings. We acknowledge your statement that none of the projects are individually significant or material to consolidated research and development expense. We do not believe that determination of project significance is limited to the amount of R&D expense incurred or to be incurred. Other factors such as the expected effects on your cash flows or results of operations which may be impacted by a new product introduction may also factor into this determination. Please disclose your criteria for deeming a project or group of related projects significant, including the qualitative and quantitative factors you considered in making this determination. Assuming that you continue to believe that no project/project group is significant, please revise your proposed disclosure to be included in MD&A to clarify this for
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all your R&D projects including those projects discussed in “pipeline” on pages 19 and 20; and to disclose the following points from your response:

- Each project represents only a small portion of the overall pipeline and none are individually significant or material;
- It is unlikely, due to the long-term nature of the project, that delays or failure in any one of the individual projects would have a material impact on results of operations or financial condition;
- You manage R&D spend in total. A delay in or termination of one project will not by itself necessarily cause you to significantly change total R&D spend.

In addition, disclose the cost for each period by therapeutic category or other descriptive class/category, and provide an estimate of the cost to complete these programs. If you do not maintain any research and development costs by therapeutic category or other descriptive class/category, disclose that fact. To the extent that costs to complete are not estimable, disclose those costs that are estimable and for those that are not estimable disclose the facts and circumstances indicating the uncertainties that preclude you from making a reasonable estimate.

Response:

In our July 12, 2010 response to comment one we agreed to provide certain additional disclosures about our pipeline in future filings. Those have been or are being addressed as noted below.

1. We believe information regarding late-stage (Phase III and submitted compounds) projects is most important to investors because these projects have the greatest potential to generate positive cash flows within the next several years. On page 27 of our June 30, 2010 Form 10-Q we disclosed a listing of new molecular entities in Phase III clinical trial testing and new molecular entities submitted for regulatory approval, as noted below:

Our new molecular entities currently in Phase III clinical trial testing include the following:

**Enzastaurin** — A small molecule for the treatment of diffuse large B-cell lymphoma

**GLP-1 Fc** — a glucagon-like peptide 1 analog for the treatment of type 2 diabetes

**Necitumumab** — a fully human monoclonal antibody being investigated as a treatment for non-small cell lung cancer

**Ramucirumab** — a monoclonal antibody being investigated as a treatment for breast and gastric cancer

**Semagacestat** — a gamma secretase inhibitor for the treatment of Alzheimer’s disease

**Solanezumab** — an a-beta antibody for the treatment of Alzheimer’s disease

**Tasisulam** — a small-molecule compound for the treatment of melanoma

**Teplizumab** — a monoclonal antibody for the treatment of type 1 diabetes

Our new molecular entities that have been submitted for regulatory review include the following:

**Arxxant** — a potential treatment for diabetic retinopathy

**Axiron** — testosterone solution to be applied via an underarm applicator, a potential treatment for testosterone deficiency

**Liprotamase** — a non-porcine pancreatic enzyme replacement therapy

2. We considered whether any of the new molecular entities disclosed in the list above had FDA submission dates that were reasonably definite and determined that none met this threshold for disclosure in our June 30, 2010 Form 10-Q. We will continue to perform this evaluation in connection with future filings, and update disclosures as appropriate.
3. Beginning with our 2010 Form 10-K, we will provide a description of each phase of development and the general time period for each. Below is a preliminary example of the language we plan to include in future filings; however, we reserve the right to revise based on further review.

#### **Phases of Development in the Pharmaceutical Industry**

##### **DISCOVERY RESEARCH PHASE**

The earliest phase of the new drug research and development process can take many years. Scientists design or identify promising molecules, screening tens of thousands of molecules for their effect on biological “targets”, which appear to play an important role in causing disease. Targets can be part of the body, such as a protein, receptor, or gene; or foreign, such as a virus or bacteria. Some targets have been proven to affect disease processes, but often the target is unproven, and may later prove to be irrelevant to the disease. Molecules which have the desired effect on the target, and meeting other design criteria, go on to the next phase of development. The probability of any one such “lead” molecule completing the rest of the drug development process and becoming a product is extremely low.

##### **EARLY DEVELOPMENT PHASE**

The early development phase involves refining lead molecules, understanding how to manufacture them efficiently, and completing initial testing for safety and efficacy. Safety testing is done first in animals and laboratory tests, to identify toxicity and other potential safety issues that would preclude use in humans. Standard predictive models are used to project these findings from laboratory tests and animals to identify potential toxicity and dosing levels for humans. The first human tests (Phase I) are normally conducted in small groups of healthy volunteers to assess safety and find the potential dosing range. After a safe dose has been established, the drug is administered to a small population of sick patients (Phase II) to look for initial signs of efficacy in treating the targeted disease and to continue to assess safety. In parallel with this testing, scientists work to identify safe, effective, and economical manufacturing processes. Long-term animal studies continue to test for potential toxicology issues. Of the molecules that enter the early development phase, typically less than 10 percent move on to the product phase of research and development. The early development phase normally takes from 6 to 8 years to complete.

## **PRODUCT PHASE**

Product phase (Phase III) molecules have already demonstrated safety and, typically, some evidence of efficacy. As a result, these molecules generally have a higher likelihood of success. These molecules are now rigorously tested in much larger patient populations to prove efficacy to a predetermined level of statistical significance. These trials are generally global in nature and are designed to generate all of the data necessary to submit the molecule to regulatory agencies for marketing approval. The new drug is generally compared with existing competitive therapies, placebo, or both. The resulting data is compiled and submitted to regulatory agencies around the world. Phase III testing varies by disease state, but can often last from 2 to 4 years.

Once submitted, the time to final marketing approval can vary from 6 months (for U.S. filing that is designated for priority review by the FDA) to several years, depending on a number of variables, such as the disease state, the strength and complexity of the data presented, the novelty of the target or compound, and the time required for the agency(ies) to evaluate the submission. There is no guarantee that a potential medicine will receive marketing approval, or that decisions on marketing approvals or indications will be consistent across geographic areas.

Regarding your comment requesting additional disclosure of R&D cost information, we do not believe such disclosure is necessary or appropriate for several reasons.

First, we do not understand the underlying rationale for any additional detailed cost disclosures. We are not a small or mid-sized pharmaceutical or biotech company with either limited resources or a small number of molecules in our pipeline. We have over \$25 billion in assets. We generate operating cash flows of several billion dollars annually, which we disclose is currently sufficient to cover our normal operating needs, including debt service, capital expenditures, acquisition activity, costs associated with litigation and government

investigations, and dividends in 2010. We do not believe it is material additional disclosure for a company that spends approximately \$4.5 billion on R&D expenses, spread over approximately 70 molecules in human clinical development and a larger number in pre-clinical development, to provide forecasted individual spend by molecule, particularly when, as described below, we manage our research and development spending as a whole.

Second, we manage our R&D spend as a whole and already disclose our overall expected spend. Due to the size of our portfolio, research and development costs for individual projects are not significant and the delay in or termination of any one project will not by itself necessarily cause us to significantly change our total R&D spend, because we prioritize R&D work across our entire pipeline and manage the spend accordingly as the projects progress. We disclose R&D expense in total and discuss significant fluctuations from the previous year in our MD&A. We also disclose forward-looking estimates of aggregate R&D spend for the coming year and update those forecasts as necessary on a quarterly basis.

Third, individual product R&D spending forecasts are highly uncertain and could be misleading. As discussed in our July 12, 2010 response, pharmaceutical research and development is lengthy and highly uncertain. That fact was confirmed for us just last week when we halted Phase III development of semagacestat, a potential treatment for Alzheimer's disease, based on clinical trial results. We have experienced numerous other examples where our actual R&D costs for drugs in development have been dramatically different than our forecasts, due to unexpected developments during clinical trials or the approval process for a molecule. Because of this high level of uncertainty, project-specific internal R&D cost projections are likely to be inaccurate, except at a macro level as we currently disclose. As a result, we do not believe that this information is valuable to users and we are concerned that it could be misleading. Even disclosing an aggregated estimate to complete these projects may be misleading to the readers of our MD&A, as it is likely that a number of molecules in our pipeline, including potentially one or more late stage molecules, will not reach commercialization.

Fourth, we believe the most important measure of our R&D efforts is the output, and investors have extensive information available. We believe that disclosure of the scientific information regarding our late-stage pipeline information is the most important information to evaluate our potential new products and we do not believe that disclosure of costs incurred by therapeutic area or in any other manner would provide much additional benefit. We believe our current MD&A disclosure, including the enhancements we have already suggested, together with the extensive scientific information we make available regarding our molecules in development, are sufficient for the investor to draw the appropriate conclusions about our pipeline.

Comment:

Financial Condition, page 25

2. Please refer to your response to comment two. Please provide us with the revised disclosure that you propose to include in future filings. We do not object to your statement that you do not propose to provide product-specific forward-looking information. However, please include in your revised disclosure the extent to

which you believe each item listed (i.e. growth in patent protected products, the emerging markets, Japan and the animal health segment) will mitigate the effect of the loss of revenues. Please clarify the fact that this growth is from your existing products that do not lose exclusivity. Please include additional information regarding your business plan for the emerging markets which supports your assertion that growth will mitigate the effect of patent losses. Also include an explanation for why you believe there will be growth in the animal health segment that will mitigate the effect of patent losses since you disclose on page 2 of the 2009 10-K that the operations of the animal health segment are not material to the financial statements. Finally, please specifically include in your revised disclosure the statement in your response that you expect rapid and severe declines in revenues of Zyprexa and Gemzar following the loss of patent exclusivity because supplies of generic substitutes are available.

Response:

In our July 12, 2010 response to comment two we agreed to provide additional disclosures in future filings and we provided the below disclosures in our June 30, 2010 Form 10-Q.

1. On page 35, under Financial Condition, we disclosed the following reference to our patent litigation discussion in our patent exclusivity discussion paragraph:

See the Hatch Waxman patent litigation discussion in Note 12 and in the “Legal and Regulatory Matters” section below.

2. On page 35, under Financial Condition, we disclosed the following update in the last sentence of our patent exclusivity discussion paragraph (updated language in bold and underlined), which also is responsive to your letter dated July 27, 2010:

However, our goal is to partially mitigate the effect on our operations, liquidity, and financial position through growth in our **patent-protected products that do not lose exclusivity during this period, the emerging markets, Japan, and our animal health segment** and the previously announced goal to reduce our expected cost structure by \$1 billion by the end of 2011.

We cannot predict the extent of future growth of each of the above listed items with reasonable certainty, sufficient to support the disclosure of individual percentages for each category. Our belief is that for the portfolio in total, the revenue growth will partially mitigate the effect of the loss of patent exclusivity. We do not believe disclosing more specific forward-looking information is appropriate, as the amounts would be subject to variability and could be unreliable.

Our practice is to disclose, in our product revenue discussion in both our 10-K and 10-Qs, significant drivers of actual growth for an individual product. For example, in the March 31, 2010 Form 10-Q we disclosed that Japan was a significant growth driver for the increase in

Alimta revenue outside the U.S. We believe our current disclosure is adequate. However, in future filings we will expand the disclosure to make clear that our expected growth in the emerging markets and Japan is attributable to both the growth of these markets and launches of patent-protected products in these markets.

Although we note in our SEC filings that our animal health segment is not material to our consolidated financial statements, we do not state that this segment will not be a contributor to growth. As discussed in our filings, we have recently entered new markets in our animal health business, including the companion animal market and the previously disclosed acquisition of animal health assets from Pfizer. As a consequence, we do expect growth in our animal health revenues.

In our June 30, 2010 Form 10-Q (on page 35) we note products that have either upcoming patent expirations (i.e. Zyprexa, Humalog and Gemzar) or patent litigation (i.e. Alimta, Cymbalta, Evista and Strattera), and state that “the loss of exclusivity of any of these compounds would result in a rapid and severe decline in revenue from the affected product.” Our practice is to provide additional, more specific, information in the event the loss of patent exclusivity is accelerated due to litigation. For example, in our June 30, 2010 Form 10-Q we updated the expected impact of an unfavorable ruling in the Gemzar patent litigation by updating the following:

- The Hatch-Waxman litigation discussion on page 21.

“In August 2009, the district court in Michigan granted a motion by Sun for partial summary judgment, invalidating our method-of-use patent. We appealed this decision, and on July 28, 2010, a panel of the Court of Appeals for the Federal Circuit affirmed the district court’s ruling. We disagree with the decision and will consider other legal options, including seeking reconsideration by the full Federal Circuit. Nevertheless, some of the generic companies, including Sun and Teva, have tentative or final marketing approval for generic gemcitabine, and therefore we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010, following the expiration of the compound patent on November 15, 2010.”
- Our product-specific revenue discussion on page 32.

“The U.S. Gemzar method-of-use patent has been held invalid by the Court of Appeals for the Federal Circuit, and various generic manufacturers have tentative or final FDA approval to market generic gemcitabine. Therefore, we expect generic gemcitabine to be introduced to the U.S. market as soon as mid-November 2010, following the expiration of the compound patent on November 15, 2010. While it is difficult to predict the precise impact on Gemzar sales, the introduction of generics would result in a rapid and severe decline in our U.S. Gemzar sales.”
- Our discussion of upcoming expected loss of patent exclusivity on page 35.

“Gemzar has already lost effective exclusivity in major European countries and we expect to lose effective exclusivity in the U.S. in November 2010”.

Additionally, in future filings we will add similar disclosure for Zyprexa. We believe these disclosures will provide adequate information to investors.

Comment:

Item 8. Financial Statements and Supplementary Data Segment Information, page 39

3. Please refer to your response to comment four. Please clarify your statement that you will disclose the “range of revenue” from each major customer since ASC 280-10-50-42 requires disclosure of the total amount of revenues from each customer for each year presented. Please provide us with the proposed disclosure to be included in future filings.

Response:

Historically we have had three customers who account for greater than 10 percent of our consolidated revenue, all of which fell into a tight (approximately five percentage points) range. Because of this narrow range, we believe disclosure of the range is appropriate to comply with the intent of the disclosure requirement and is adequate for a reader to gain an understanding of the impact our significant customers have on our consolidated total revenue. Therefore, we propose to revise our disclosure in future filings as follows:

In 2010, 2009, and 2008, our three largest wholesalers each accounted for between 12 percent and 17 percent of consolidated total revenue.

To be clear, we are presenting the information in this way because we believe the tight range allows us to comply with the intent of the disclosure in a manner that is more concise and easier to read. If the range were to widen to the point where this was no longer the case, we would disclose the percentage for each customer for each year.

Comment:

Notes to Consolidated Financial Statements

Note 12: Income Taxes, page 65

4. Please refer to your response to comment six. Please confirm that you will revise the disclosure in future filings to clarify that there are no individually significant items classified as ‘Other’.



Response:

ASC 740-10-50-6 states “A public entity shall disclose the approximate tax effect of each type of temporary difference and carryforward that gives rise to a significant portion of deferred tax liabilities and deferred tax assets (before allocation of valuation allowances).” We understand this guidance to require us to disclose only the significant items in our deferred tax asset disclosure, which we did in our 2009 Form 10-K. We do not believe that we are required to make a statement confirming there are no individually significant items classified as “Other” and we believe that by remaining silent that fact is implied. Our concern with providing the specific language that you proposed is that there are numerous disclosures that we don’t provide because they are immaterial for us, and we are hesitant to add this type of disclosure because we do not want to create an expectation that we will always specifically inform the reader that something is not material for us. Please inform us if you believe we are misinterpreting the guidance.

Comment:

Note 13: Retirement Benefits, page 67

5. Please refer to your response to comment seven. Please provide us with the proposed revised disclosure that includes the inputs used to determine the fair value of Level 3 plan assets in 2009.

Response:

Our level 3 investments consist primarily of interests in private hedge funds and private equity-like investments. In future filings we will supplement the description of these two categories of investments in the Benefit Plan Investments section of Note 13 with the following discussion of specific inputs to valuing these two types of investments.

Plan holdings in hedge funds are valued based on net asset values (NAVs) calculated by each fund or general partner, as applicable, and we have the ability to redeem these investments at NAV within the near term.

Plan holdings in private equity-like investments are valued using the value reported by the partnership, adjusted for known cash flows and significant events through our reporting date. Values provided by the partnerships are primarily based on analysis of and judgments about of the underlying investments. Inputs to these valuations include underlying NAVs, discounted cash flow valuations, comparable market valuations, and may also include adjustments for currency, credit, liquidity and other risks as applicable. The vast majority of these private partnerships provide us with annual audited financial statements including their compliance with fair valuation procedures in compliance with applicable accounting standards.

Comment:

6. Please refer to your response to comment eight and your proposed disclosure. Since the asset allocation study is only performed every 3 to 4 years please revise your proposed disclosure to clarify whether any adjustments were made to the overall rate of return on plan assets assumption during the years when the asset allocation study was not performed. We believe to comply with the disclosure requirements of ASC 715-20-50-1 you should more fully explain how you arrived at 8.8% and 9.0% assumptions when your 20-year rate of return was 8.3%.

Response:

Although the asset allocation study is only performed every 3 to 4 years, we do consider asset allocation every year when evaluating the rate of return on plan assets assumption.

In our current disclosure we noted that the 20-year annualized rate of return on our U.S. plans includes investment losses in 2001, 2002, and 2008, years which experienced significant and unprecedented declines in the financial markets. We believe that achieving an 8.3% 20-year rate of return in light of the unprecedented market declines noted above during this period helps support our 8.8% and 9.0% future return assumption.

We will revise our disclosure in future filings to reflect your comments, as follows.

“In evaluating the expected return on plan assets annually we consider numerous factors, including; our historical assumptions compared with actual results, an analysis of current and future market conditions, our current and expected asset allocations, historical returns and the views of leading financial advisers and economists for future asset class returns. As noted, historical returns are just one of several factors considered and are not the starting point for determining the expected return.”

Comment:

Form 10-Q March 31, 2010

Notes to Consolidated Condensed Financial Statements

Note 4: Collaborations

Boehringer Ingelheim, page 11

7. Please refer to your response to comment eleven. Please revise your disclosure to clarify that the royalties to be paid through 2012 are contingent payments and were part of the negotiated cost of reacquiring the marketing rights. Disclose the pattern of amortization you are using (straight line, accelerated, etc.) and why that method is the most appropriate.

Response:

In response to your letter dated July 27, 2010 we disclosed on page 8, under Note 4, Boehringer Ingelheim, the following update in the next to last sentence of our collaboration paragraph (updated language in bold and underlined or struck through):

In connection with the arrangement, we paid BI approximately \$400 million and will also pay ~~a royalty~~ to BI a percentage of our sales of duloxetine in these countries through 2012 **as consideration for the rights acquired.**

Additionally, we will disclose in future filings that we are amortizing this amount using the straight-line method.

For your information, when determining the amortization method for the intangible asset acquired, we considered ASC 350-30-35-6 and determined that the straight-line method resulted in a pattern of amortization that was materially consistent with the pattern in which we anticipate the economic benefits of the intangible asset will be used up; however, we do not believe GAAP requires us to disclose this information and we prefer not to make this disclosure if it is not required. Please inform us if you believe we have misinterpreted the guidance.

We will be following this letter with a call to discuss our responses.

In the meantime, if you have any questions about these responses or require additional information, please contact me at 317-276-2024.

Sincerely,

ELI LILLY AND COMPANY

/s/ Arnold C. Hanish

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Vice President, Finance and  
Chief Accounting Officer