

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

## VIA EDGAR

#### May 10, 2011

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, 2010 File Number 001-06351

#### Dear Mr. Rosenberg:

Eli Lilly and Company (Lilly) submits this response to your letter dated April 13, 2011 commenting on our Form 10-K for the year ended December 31, 2010. For ease of reference we have repeated your comments prior to our responses.

#### Comment:

Item 7. Management's Discussion and Analysis Results of Operations and Financial Condition Executive Overview, page 17

- 1. In order to help us evaluate your disclosure about research and development activities, please provide us with the following information:
  - Tell us the status of determining if your R&D expense tracking is reliable and accurate enough to disclose the percent of R&D spend on pre- and post-clinical projects, as indicated in your November 9, 2010 response to us.
  - Please tell us, of the more than 65 potential new drugs in human testing, the number of those in phase III and the number submitted for regulatory review. For those potential new drugs in phase III or submitted for regulatory review not listed on page 18, tell us why you did not list them.
  - For your late stage projects listed on page 18, tell us the month and year that each project entered the respective phase, and identify for us any significant patents associated with each project and respective expiration date.

## Response:

We have numbered our responses to correlate with the bullets in your comments.

1. As noted in our November 9, 2010 response, we manage our R&D spend in total at a macro level, not by therapeutic area or by project. We have determined that our R&D expense tracking for pre- and post-clinical projects is not reliable and accurate enough to disclose in an SEC filing. Upon further investigation we found that we have the same limitations in obtaining this information as we do in determining costs by therapeutic area, which we addressed with you in your review of our 2009 Form 10-K. The reliability of our current expense tracking is sufficient for our business needs. As we previously discussed and as we noted in our December 20, 2010 response, we added the below language to our 2010 Form 10-K:

While we do accumulate certain research and development costs on a project level for internal reporting purposes, we must make significant cost estimations and allocations, some of which rely on data that is neither reproducible nor validated through accepted control mechanisms. As a consequence, we do not have sufficiently reliable data to report on total research and development costs by therapeutic category.

Given our facts and circumstances, we believe our current disclosure is adequate and appropriate.

2. The lists provided on page 18 are complete lists of the new molecular entities (NMEs or new drugs) that are in Phase III clinical testing or that have been submitted for regulatory review.

In our March 31, 2011 Form 10-Q, we clarified this fact by revising our introduction to the Phase III NME listing as follows (and revised the submitted NME listing introduction similarly):

The following new molecular entities are currently in Phase III clinical trial testing

We will continue to update these lists quarterly and we believe our current disclosure is adequate.

3. Information regarding specific NME clinical studies (including the name of the NME, the sponsor, and the phase of the study) is publicly available on <u>www.clinicaltrials.gov</u>. This information is current and publicly available to investors as this information must be updated within 30 calendar days of a status change in accordance with the FDA Amendments Act of 2007. Therefore, we feel our current disclosure is adequate.

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For your information, the list below includes the quarter when each NME from our Phase III and submitted lists entered the respective phase.

NMEs that are currently in Phase III clinical trial testing:

BAFF antibody—Q4 2010 BI10773—Q3 2010 Enzastaurin—Q1 2006 GLP-1 Fc— Q3 2008 mGlu2/3— Q1 2011 Necitumumab— Q4 2009 NERI—Q4 2010 Ramucirumab— Q4 2009 Solanezumab— Q2 2009

NMEs that have been submitted for regulatory review:

Arxxant— Q1 2006 Florbetapir—Q3 2010 Linagliptin—Approval received May 2, 2011 and will be removed from this list in future filings Liprotamase—Q1 2010

We do disclose activities that have occurred during the year that affect NMEs in our late stage pipeline, which, when combined with the R&D discussion in the Form 10-K, provides the reader information on the current development status of a NME but does not speculate on the timing of commercial launch.

We disclose the most relevant patent protection for our major marketed products on page 5 of our 2010 Form 10-K. Estimating the effective market exclusivity for a medicine prior to commercial launch is problematic for a host of reasons.

- The effective patent exclusivity will vary by country due to variations in patent laws, the timing of the original patent filings made in that country, and the scope of protection that is ultimately secured in each country.
- In the United States, the patent expiration date may be difficult to assess prior to the actual issuance of the patent due to the patent term adjustment that may be applicable under U.S. patent laws arising from review at the U.S. Patent and Trademark Office.
- Similarly, under the Hatch-Waxman Patent Term Restoration Act of 1984, a period of patent term restoration may be added based on the length of the regulatory review period before the FDA. The period is fixed only when actual regulatory approval is secured. Predicting regulatory approval dates is highly speculative.

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Under the new Biologics Price Competition and Innovation Act of 2010, biologic products may receive data-based exclusivity for 12 years after FDA marketing approval. Again, it is highly speculative to predict the timing of marketing approvals.

As such, we believe our current practice of disclosing patent expiration dates once a drug becomes commercialized is appropriate and adequate.

#### Comment:

### Item 8. Financial Statements and Supplementary Data Notes to Consolidated Financial Statements Note 15. Contingencies, page 69

- 2. You disclose while it is not possible to determine the outcome of these matters, you believe that, except as specifically noted below, the resolution of all such matters will not have a material adverse effect on your consolidated financial position or liquidity, but could possibly be material to your consolidated results of operations in any one accounting period. We do not believe this disclosure satisfies the criteria in ASC 450-20-50. Please revise your disclosure to disclose one of the following for reasonably possible losses.
  - The amount or range of reasonable possible losses in addition to the amount accrued; or
  - The amount cannot be estimated.

Please tell us whether you have factored insurance recoveries (possible or otherwise) in your estimate of reasonable possible losses and, if so, to what extent.

#### Response:

While we did not use the exact words of the standard, we believe the introduction to our contingencies footnote informs investors that we cannot estimate the amount or the range of reasonably possible losses and, therefore, complies with ASC 450-20-50. To be more clear, in future filings we will add the following to our introduction (as noted by underline and bold font):

It is not possible to determine the outcome of these matters and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these matters; however, we believe that, except as specifically noted below, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

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For those cases for which we have insurance, the liabilities accrued are in excess of the recoveries. We have separately recorded the gross liability (as a liability) and the expected gross insurance recovery (as an asset) on the balance sheet.

## Comment:

## Zyprexa Litigation, page 70 Other Product Liability Litigation, page 71

3. You disclose that you are prepared to continue your vigorous defense of Zyprexa in all remaining claims, consisting of approximately 70 lawsuits in the U.S. covering approximately 150 plaintiffs, of which about 50 lawsuits covering about 50 plaintiffs are part of the MDL, and that you have a trial scheduled in Texas State court in August 2011. You also disclose that you have been named as a defendant in numerous other product liability lawsuits involving primarily diethylstilbestrol (DES), thimerosal, and Byetta and approximately a third of these claims are covered by insurance, subject to deductibles and coverage limits. Please revise your disclosure regarding both Zyprexa and other product liability litigation to include all of the disclosures required by paragraphs 3-5 of ASC 450-20-50 related to your litigation and governmental inquiries. Specifically, if an unfavorable outcome is determined to be reasonably possible but not probable, or if the amount of loss cannot be reasonably estimated, accrual would be inappropriate, but disclosure must be made regarding the nature of the contingency and an estimate of the possible loss or range of possible loss or state that such an estimate cannot be made.

## Response:

Both the "Zyprexa Litigation" and the "Other Product Liability Litigation" are part of the contingencies footnote and follow the introductory paragraph described above in our response to Comment 2, which will clarify that we cannot estimate the range of possible loss.

## Comment:

# Item 9A. Controls and Procedures

# Changes in Internal Controls, page 76

4. Please tell us the intent of your disclosure about the multi-year initiative and the possible increase in risks in the short-term as it appears to qualify your statement that, during the fourth quarter of 2010, there were no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, internal control over financial reporting.



#### Response:

The intent of our disclosure of the multi-year initiatives and the related potential increase in short-term risks is a prospective disclosure to the reader of the actions we are taking to improve our worldwide financial reporting and the overall control environment. Actions undertaken during 2010 did not materially affect the internal control over financial reporting in the fourth quarter of 2010 and are not reasonably expected to materially affect internal control in the future. We will continue to monitor our controls over financial reporting quarterly, consistent with past practice and will disclose any change that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We acknowledge that:

- we are responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- we may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

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 Arnold C. Hanish Vice President, Finance and Chief Accounting Officer