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

VIA EDGAR

June 22, 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
Filed February 22, 2011
File Number 001-06351

Dear Mr. Rosenberg:

Eli Lilly and Company (Lilly) submits this response to your letter dated May 24, 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

Executive Overview

Late-Stage Pipeline, page 17

1. Refer to your response to prior comment one, and address the following for your research and development activities:
 - Please provide us proposed disclosure to be included in future periodic reports that indicates that you also do not have reliable data in order to disclose the amount incurred for pre-clinical versus clinical costs. Rather than disclosing that you do not have reliable data to disclose by therapeutic class or for pre-clinical versus clinical; if you believe there is other data other than on a therapeutic or on pre-clinical versus clinical basis that you have disclose to convey the nature of research and development expense in order to improve disclosure regarding where resources are used for research and development activities, please provide us proposed disclosure to be included in future periodic reports.

- Please confirm that you will disclose in future periodic reports the quarter when each new molecular entity currently in Phase III clinical trial testing entered that phase and the quarter when each new molecular entity submitted for regulatory review was submitted. We believe that this information, which is readily available and which you indicate is made publicly available elsewhere, would provide additional context about the pipeline. In addition, if you believe that it is necessary to supplement this disclosure about timing of these events in order to put it in context or to inform how it may or may not be relied upon to predict future events, please provide us disclosure in the form of proposed disclosure to be included in future periodic reports.
- We acknowledge the patent term may fluctuate for some of the reasons you have set forth on pages three and four of your response; however, it would seem that the remaining patent life is a significant factor in evaluating pipeline projects. As previously requested, please provide us the information regarding patents for each of the late stage projects. If you do not know and cannot estimate the remaining patent life for a particular patent(s) associated with a project(s), please tell us the specific facts and circumstances for the particular patent(s).

Response:

To be able to clearly address your comments, we have assigned a letter identification to the above bullet points to clarify the specific points within comment one we are addressing.

- A) In response to your comments on our 2010 Form 10-K, we added discussion about how research and development expense is managed.

In future filings, we will revise our disclosure in response to your above comment as follows:

We manage research and development spending across our portfolio of molecules, and a delay in, or termination of, one project will not by itself necessarily cause a significant change in our total research and development spending. Due to the risks and uncertainties involved in the research and development process, we cannot reliably estimate the nature, timing, completion dates, and costs of the efforts necessary to complete the development of our research and development projects, nor can we reliably estimate the future potential revenue that will be generated from a successful research and development project. Each project represents only a portion of the overall pipeline and none are individually material to our consolidated research and development expense. 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 total research and development costs **by project, by pre-clinical versus clinical spend, or** by therapeutic category.

- B) In future periodic reports we will disclose the quarter when each new molecular entity currently in Phase III clinical trial testing entered that phase and the quarter when each new molecular entity submitted for regulatory review was submitted.
- C) In future periodic reports on Form 10-K, we will enhance our discussion in “Patent, Trademarks, and Other Intellectual Property Rights” as follows:

Overview

Intellectual property protection is critical to our ability to successfully commercialize our life sciences innovations and invest in the search for new medicines. We own, have applied for, or are licensed under, a large number of patents in the U.S. and many other countries relating to products, product uses, formulations, and manufacturing processes. There is no assurance that the patents we are seeking will be granted or that the patents we hold would be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. In addition, competitors or other third parties sometimes may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property.

Outside the U.S., the adequacy and effectiveness of intellectual property protection for pharmaceuticals varies widely. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization (WTO), over 140 countries have now agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to all patent owners. Because of TRIPs transition provisions, dispute resolution mechanisms, and substantive limitations, it is difficult to assess when and how much, if at all, we will benefit commercially from this protection.

The patent protection that is anticipated to be of most relevance to investigational new medicines in our pipeline are national patents, particularly those in major markets such as the U.S., various European countries and Japan. These patents may be issued based upon the filing of international patent applications, usually filed under the Patent Cooperation Treaty (PCT). In general, national patents in each relevant country are available for a period of 20 years from the filing date of the PCT application. Further patent term adjustments and restorations may extend the 20-year period. Other patents and regulatory or marketing exclusivity may also apply to these investigational medicines.

Patent term adjustment is a statutory right provided to all U.S. patent applicants to provide relief in the event the patent undergoes delayed examination within the United States Patent and Trademark Office.

Patent term restoration is a statutory right provided to U.S. patents that claim inventions subject to review by the FDA. A single patent for a pharmaceutical product may be eligible for patent term restoration, to make up for a portion of the time invested in clinical trials and the FDA review process. Patent term restoration is limited by a formula and cannot be calculated until product approval due to uncertainty about the final duration of clinical trials and the time it takes the FDA to review an application. There is a five year cap on any restoration as well as total proscriptio against any patent being extended for more than fourteen years beyond approval.

In addition to patent exclusivity, regulatory authorities in major markets generally grant marketing exclusivity for a period of years in recognition of the substantial investment required to complete clinical trials. Data exclusivity for small molecule new chemical entities is five years in the U.S., ten years in the European Union and eight years in Japan. This period of exclusivity runs concurrently with the patent term for any relevant patent.

When a product patent expires, the patent holder often loses effective market exclusivity for the product. This can result in a severe and rapid decline in sales of the product, particularly in the U.S. However, in some cases the innovator company may achieve exclusivity beyond the expiry of the product patent through manufacturing trade secrets, later-expiring patents on methods of use or formulations, or data-based exclusivity that may be available under pharmaceutical regulatory laws.

Some of our current products, including Erbitux, Forteo, ReoPro, and Xigris, and many of the potential products in our research pipeline, are biological products (“biologics”). Based on the Biologics Price Competition and Innovation Act (enacted in the U.S. in 2010), the FDA now has the authority to approve similar versions (“biosimilars”) of innovative biologic products. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic, address the challenges of biologics manufacturing, and include a certain amount of safety and efficacy data which FDA will determine on a case-by-case basis. Under the data protection provisions of this law, FDA cannot approve a biosimilar application until 12 years after initial marketing approval of the innovator biologic. Regulators in the EU and other countries also have been given the authority to approve biosimilars. The extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar

to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Comment:

Notes to Consolidated Financial Statements

Note 15, Contingencies, page 69

Zyprexa Litigation, page 70

Other Product Liability Litigation, page 71

2. Refer to your response to prior comments two and three. Regarding your proposed disclosure to be included in future filings that “we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these matters,” please revise the phrase “for these matters” to state, if true, “for any of these matters.” In this regard, if there are any matters you can reasonably estimate, disclosure is required of those estimates for those matters.

Response:

In future filings, we will revise our disclosure accordingly and we will continue to disclose estimates of the range of possible loss for any of these matters where we can make reasonable estimates.

We also understand, from our telephonic conversation on June 15, 2011, that you would like us to explain why it is difficult to reasonably estimate a range of loss for litigation contingencies. As we discussed, every quarter senior financial reporting management meet with internal legal counsel regarding litigation and discuss these matters with our external SEC legal counsel. Once we are able to reasonably estimate the bottom of the range or a best estimate for losses that are probable, we record the expense and accrue the liability in accordance with ASC 450. In these instances, we often conclude that the upper end of the range cannot be reasonably estimated. We do not believe that an amount claimed by a plaintiff (or the others, including the government) or offered in a settlement discussion, is sufficient alone to indicate a reasonable estimate of a potential loss, nor do such demands indicate a probable loss. For us to disclose these amounts as the upper end of a range, if known, would be misleading to investors since many are unreasonable relative to the claimed injury, especially at the outset of the matter.

No reasonable estimate of the possible loss or range of loss in excess of amounts accrued, if any, could be made for the matters disclosed in the contingencies footnote to our most recent financial statements. Legal proceedings are inherently unpredictable in nature and this may be exacerbated by various factors, including, for example: (i) the damages sought in the proceedings are unsubstantiated or indeterminate and may be extraordinarily punitive; (ii) discovery is not complete; (iii) the proceeding is in its early stages; (iv) the matters present legal uncertainties; (v) there are significant facts in dispute; (vi) the choice of judge; (vii) the jury pool; or (viii) the potential for a wide range of outcomes.

To reaffirm our statement during our telephonic discussion, we do consider on a quarterly basis whether we can reasonably estimate the range of potential losses of our material loss contingencies. Additionally, we would disclose this range as required by ASC 450 if we could reasonably estimate the range of potential losses.

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
Vice President, Finance and
Chief Accounting Officer