



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

**VIA EDGAR**

May 7, 2014

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, 2013  
Filed February 19, 2014  
File Number 001-06351

Dear Mr. Rosenberg:

Eli Lilly and Company (Lilly) respectfully submits this response to your letter dated April 10, 2014 commenting on our Form 10-K for the year ended December 31, 2013. For ease of reference, we repeat your comments prior to our responses.

**Notes to Consolidated Financial Statements**

**Note 4: Collaborations, page 53**

**1. Please refer to the first paragraph herein.**

- **You indicate that collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. Tell us your accounting policies regarding separation and allocation for your collaborative arrangements.**
- **Although you disclose your accounting policies for income you generate as a result of collaboration agreements under "revenue recognition" in Note 1 Summary of Significant Accounting policies, tell us your accounting recognition for other aspects of these arrangements and where these policies are disclosed.**

Response:

In response to your request in the first bullet point:

Pursuant to our conversation with Tabatha McCullom, Staff Accountant at the SEC, on April 14, 2014, our understanding is that your request regarding accounting policies for the separation and allocation for our collaborative arrangements is in regards to revenue recognition for multiple-element arrangements.

We account for our revenue arrangements that include multiple elements in accordance with ASC 605-25, *Revenue Recognition - Multiple Element Arrangements*. To clarify our policy for the separation and allocation of revenues related to arrangements subject to multiple-elements, we will enhance our policy disclosure for multiple-element arrangements in our Note 1, "Summary of Significant Accounting Policies" beginning with our Annual Report on Form 10-K for the year ended December 31, 2014, so that it is substantially as set forth below (underlined text represents language in addition to existing disclosures):

"In arrangements involving the delivery of more than one element, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. Our determination is based on whether the deliverable has "standalone value" to the customer. If multiple activities, rights, or deliverables do not have standalone value, they are combined into a single unit of accounting. The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable."

In response to your request in the second bullet point:

The accounting recognition for expenses and milestone payments made under these arrangements follow our standard policies as described in Note 1. A summary of the accounting policy and where these items are disclosed in Note 1 follows:

- Research and development costs, as well as acquired IPR&D in an asset acquisition which has no alternative future use are expensed as incurred, as disclosed under the caption, "*Research and development expenses and acquired IPR&D.*"
- Upfront and pre-regulatory approval milestone payment obligations are expensed when the event requiring payments occurs, as disclosed under the caption, "*Research and development expenses and acquired IPR&D.*"
- Post-regulatory approval milestone payment obligations are capitalized and amortized over the remaining useful life of the underlying asset, as disclosed under the caption, "*Goodwill and other intangibles.*"

The accounting recognition of cost reimbursements and profit-sharing payments is described in Note 4 as follows:

- In the first paragraph of Note 4, we provide the following description of our accounting policy for the cost reimbursement aspects of collaborations:

*"Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item, net of any payments made to or reimbursements received from our collaboration partners."*

- The accounting for the profit-sharing payments is described in Note 4 in the discussion of each individual arrangement that contains a profit-sharing aspect.

We believe our disclosures in Note 4 provide users with a roadmap of our accounting recognition for each significant component of the specific arrangements disclosed. To assist you in identifying these specific

disclosures, please refer to Attachment A, which is a copy of Note 4 from our 2013 Annual Report on Form 10-K in which we highlight these accounting disclosures for the significant components of our arrangements.

**2. We acknowledge the following for amounts related to collaborative arrangements:**

- **In the first paragraph herein, the consolidated amount of collaboration and other revenue related to all of your collaborative arrangements;**
- **Within the separate discussions of your more significant arrangements, the amounts included in net product sales and collaboration and other revenue and, in the case of Exenatide, the amount included in other-net, (income) expense; and**
- **In the last paragraph herein, commission and profit-share payments included in marketing, selling, and administrative expense.**

**Your disclosure indicates that there are other amounts related to your arrangements recorded within your financial statements. In order to help us understand more fully how your collaborative arrangements impact your financial statements for each period presented, please provide us, in table format, the amounts in the above bullets and other amounts by year and by line item included in your statements of operations attributable to transactions arising from collaborative arrangements between you and other participants and third-parties. Please provide separate tables for each of your "significant" collaborative arrangements and for all of your collaborative arrangements in the aggregate (i.e. the "significant" arrangements and all other arrangements). Present separately amounts with other participants and third-parties that are netted in a financial statement line item.**

Response:

A portion of our response to Comment Number 2 (Attachment B) is being submitted separately pursuant to a request for confidential treatment under Rule 83 of the Commission's Rules Concerning Information and Requests.

Please refer to Attachment B (filed separately) for the requested tables. The following is a summary of the information compiled in the Attachment B tables:

- "Significant" collaborations represent the individual arrangements that we disclose in Note 4 of our Annual Report on Form 10-K. These arrangements include those that meet the definition of a collaboration under ASC 808, *Collaborative Arrangements*, as well as other notable arrangements with third parties.
- "All Other" collaborations represent all other identified arrangements that meet the definition of a collaboration under ASC 808.
- Amounts included in each "Direct by Lilly" row represent revenues or expenses recognized/incurred by Lilly where Lilly is principal to a contract with a third party for the specific element. Sales of product to a collaborative partner are included within this caption.
- Amounts included in each "Payments to (from) partner" row represent net revenues or net expenses that arise from transactions between Lilly and our partners in the arrangements (with the exception of the aforementioned sales of product to a collaborative partner which are included in the "Direct by Lilly" caption). These may include royalties, profit sharing, cost reimbursements,

amortization of upfront payments to the partner, and milestones. Amounts included within this caption are accounted for on an accrual basis.

- Amounts included in each "net recorded" row represent the amounts related to the arrangement as they are included in the individual line items in our statement of operations (ie. the sum of the "Direct by Lilly" and "Payments to/from partner" rows).

We'd like to highlight the following regarding the information provided for our collaborations and other arrangements:

- In the aggregate, "All Other" collaborations represent 1% or less of consolidated revenues and expenses for each period presented. We believe these arrangements are inconsequential to our consolidated results of operations and cash flows and are immaterial for disclosure purposes.
- We believe total reductions to line items in our statements of operations resulting from netting of collaborative transactions are immaterial.
- All individually material amounts paid/received between the parties pursuant to each collaboration have been disclosed.

We acknowledge that:

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

If you have any questions about these responses or require additional information, please contact me at 317-651-2310.

Sincerely,

ELI LILLY AND COMPANY

Donald A. Zakrowski  
Vice President, Finance and  
Chief Accounting Officer

## Attachment A - 2013 10-K, Note 4: Collaborations

The following is a copy of Note 4 from our 2013 Annual Report on Form 10-K. We highlight, in yellow, accounting disclosures for each significant component of the arrangements disclosed.

### Note 4: Collaborations

We often enter into collaborative arrangements to develop and commercialize drug candidates. Collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. These collaborations often require milestone and royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements or payments to the third party. Revenues related to products we sell pursuant to these arrangements are included in net product sales, while other sources of revenue (e.g., royalties and profit-share payments) are included in collaboration and other revenue. For the years ended December 31, 2013, 2012, and 2011, we recognized collaboration and other revenue of \$707.5 million, \$633.0 million, and \$681.7 million, respectively. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item, net of any payments made to or reimbursements received from our collaboration partners. Each collaboration is unique in nature, and our more significant arrangements are discussed below.

#### Exenatide

In November 2011, we agreed with Amylin Pharmaceuticals, Inc. (Amylin) to terminate our collaborative arrangement for the joint development, marketing, and selling of Byetta® (exenatide injection) and other forms of exenatide such as Bydureon® (exenatide extended-release for injectable suspension). Under the terms of the termination agreement, Amylin made a one-time, upfront payment to us of \$250.0 million. Amylin also agreed to make future revenue-sharing payments to us in an amount equal to 15.0 percent of its global net sales of exenatide products until Amylin made aggregate payments to us of \$1.20 billion plus interest, which would accrue at 9.5 percent. Upon completion of the acquisition of Amylin by Bristol-Myers Squibb Company in August 2012, Amylin's obligation of \$1.26 billion, including accrued interest, was paid in full, with \$1.21 billion representing a prepayment of the obligation. We would also receive a \$150.0 million milestone payment contingent upon U.S. Food and Drug Administration (FDA) approval of a once-monthly suspension version of exenatide.

Commercial operations were transferred to Amylin in the U.S. in late-2011. Outside the U.S., we transferred to Amylin exenatide commercial rights and control in all markets during the first quarter of 2013.

Payments received from Amylin were allocated 65 percent to the U.S., which was treated as a contract termination, and 35 percent to the business outside the U.S., which was treated as the disposition of a business. The allocation was based upon relative fair values. The revenue-sharing income allocated to the U.S. was recognized as collaboration and other revenue, consistent with our policy for royalty revenue, while the income related to the prepayment of Amylin's obligation allocated to the U.S. was recognized in other-net, (income) expense. All income allocated to the business outside the U.S. that was transferred during the first quarter of 2013 was recognized as a gain on the disposition of a business in other-net, (income) expense, net of the goodwill allocated to the business transferred.

Prior to termination of the collaboration, we and Amylin were co-promoting Byetta in the United States. Amylin was responsible for manufacturing and primarily utilized third-party contract manufacturers to supply Byetta. We supplied Byetta pen delivery devices for Amylin and will continue to do so for a period that will not extend beyond the first quarter of 2014. We were responsible for certain development costs related to certain clinical trials outside the U.S. that we were conducting as of the date of the termination agreement as well as commercialization costs outside the U.S. until the commercial rights were transferred to Amylin.

Under the terms of our prior arrangement, we reported as collaboration and other revenue our 50 percent share of gross margin on Amylin's net product sales in the United States. We reported as net product sales 100 percent of sales outside the U.S. and our sales of Byetta pen delivery devices to Amylin. We paid Amylin a percentage of the gross margin of exenatide sales outside of the U.S., and these costs were recorded in cost of sales. This arrangement for the commercial operations outside the U.S. continued until those rights were transferred to Amylin during the first quarter of 2013. Prior to termination of the agreement, under the 50/50 profit-sharing arrangement for the U.S., in addition to recording as revenue our 50 percent share of exenatide's gross margin, we also recorded approximately 50 percent of U.S. related research and development costs and marketing and selling costs in the respective line items on the consolidated statements of operations.

In accordance with the prior arrangement and pursuant to Amylin's request, we loaned Amylin \$165.0 million in the second quarter of 2011. This loan and related accrued interest were paid in full in August 2012.

The following table summarizes the revenue and other income recognized with respect to exenatide:

	2013	2012	2011
Net product sales	\$ 133.1	\$ 207.8	\$ 179.6
Collaboration and other revenue	—	70.1	243.1
<b>Total revenue</b>	<b>\$ 133.1</b>	<b>\$ 277.9</b>	<b>\$ 422.7</b>
Income related to termination of the exenatide collaboration with Amylin <sup>(1)</sup>	\$ 495.4	\$ 787.8	\$ —

<sup>1</sup> Presented in other-net, (income) expense

### Effient®

We are in a collaborative arrangement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) to develop, market, and promote Effient. We and Daiichi Sankyo co-promote Effient in certain territories (including the U.S. and five major European markets), while we have exclusive marketing rights in certain other territories. Daiichi Sankyo has exclusive marketing rights in Japan and certain other territories. The parties share approximately 50/50 in the profits, as well as in the costs of development and marketing in the co-promotion territories. A third party manufactures bulk product, and we produce the finished product for our exclusive and co-promotion territories. **We record product sales in our exclusive and co-promotion territories.** In our exclusive territories, we pay Daiichi Sankyo a royalty specific to these territories. **Profit-share payments made to Daiichi Sankyo are recorded as marketing, selling, and administrative expenses. All royalties paid to Daiichi Sankyo and the third-party manufacturer are recorded in cost of sales.** Effient sales were \$508.7 million, \$457.2 million, and \$302.5 million for the years ended December 31, 2013, 2012, and 2011, respectively.

### Erbix®

We have several collaborations with respect to Erbitux. The most significant collaborations are in the U.S., Canada, and Japan (Bristol-Myers Squibb Company); and worldwide except the U.S. and Canada (Merck KGaA). Upon expiration of the agreements, all of the rights to Erbitux in the U.S. and Canada return to us and certain rights to Erbitux outside the U.S. and Canada will remain with Merck KGaA (Merck).

The following table summarizes our revenue recognized with respect to Erbitux:

	2013	2012	2011
Net product sales	\$ 58.5	\$ 76.4	\$ 87.6
Collaboration and other revenue	315.2	320.6	321.6
<b>Total revenue</b>	<b>\$ 373.7</b>	<b>\$ 397.0</b>	<b>\$ 409.2</b>

### Bristol-Myers Squibb Company

Pursuant to commercial agreements with Bristol-Myers Squibb Company and E.R. Squibb (collectively, BMS), we are co-developing Erbitux in the U.S. and Canada with BMS through September 2018, exclusively, and in Japan with BMS and Merck through 2032. Under these arrangements, Erbitux research and development and other costs are shared by both companies according to a predetermined ratio.

Responsibilities associated with clinical and other ongoing studies are apportioned between the parties under the agreements. **Collaborative reimbursements received by us for supply of clinical trial materials; for research and development; and for a portion of marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated statement of operations. We receive a distribution fee in the form of a royalty from BMS, based on a percentage of net sales in the U.S. and Canada, which is recorded in collaboration and other revenue. Royalty expense paid to third parties, net of any reimbursements received, is recorded as a reduction of collaboration and other revenue.**

We are responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient (API) for clinical and commercial use in the U.S. and Canada, and BMS will purchase all of its requirements of API for commercial use from us, subject to certain stipulations per the agreement. **Sales of Erbitux to BMS for commercial use are reported in net product sales.**

A development and license agreement grants Merck exclusive rights to market Erbitux outside of the U.S. and Canada, and expires in December 2018. A separate agreement grants co-exclusive rights among Merck, BMS and us in Japan and expires in 2032.

Merck manufactures Erbitux for supply in its territory as well as for Japan. We receive a royalty on the sales of Erbitux outside of the U.S. and Canada, which is included in collaboration and other revenue as earned. Collaborative reimbursements received for research and development and for marketing, selling, and administrative expenses are recorded as a reduction to the respective expense line items on the consolidated statement of operations. Royalty expense paid to third parties, net of any royalty reimbursements received, is recorded as a reduction of collaboration and other revenue.

### Diabetes Collaboration

In January 2011, we and Boehringer Ingelheim entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Currently, the compounds included in the collaboration are Boehringer Ingelheim's two oral diabetes agents, linagliptin and empagliflozin, and our new insulin glargine product. Additionally, Boehringer Ingelheim may elect to opt in to the Phase III development and potential commercialization of our anti-TGF-beta monoclonal antibody. Under the terms of the global agreement, we made an initial one-time payment to Boehringer Ingelheim of \$388.0 million and recorded an acquired IPR&D charge, which was included as expense in the first quarter of 2011 and was deductible for tax purposes.

Linagliptin was subsequently approved in 2011 and launched in the U.S. (trade name Tradjenta®), Japan (trade name Trazenta™), certain countries in Europe (trade name Trajenta®), and other countries. Currently, empagliflozin and the new insulin glargine product are both under regulatory review in the U.S., Europe, and Japan, and the anti-TGF-beta monoclonal antibody is in Phase II clinical testing.

In connection with the approval of linagliptin in the U.S., Japan, and Europe, in 2011 we paid \$478.7 million in success-based regulatory milestones, all of which were capitalized as intangible assets and are being amortized to cost of sales. We incurred milestone-related expenses of \$97.2 million in connection with regulatory submissions for empagliflozin in the U.S., Europe, and Japan during 2013. These regulatory submission milestones were recorded as research and development expenses. We may also pay up to 225.0 million euro in additional success-based regulatory milestones for empagliflozin.

During 2013, we earned \$50.0 million in milestones for the regulatory submissions of our new insulin glargine product in the U.S., Europe, and Japan. These submission milestones were recorded as income in other-net, (income) expense. In the future, we will be eligible to receive up to \$250.0 million in success-based regulatory milestones on our new insulin glargine product.

Should Boehringer Ingelheim elect to opt in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, we would be eligible for up to \$525.0 million in opt-in and success-based regulatory milestone payments.

The companies share ongoing development costs equally. The companies also share in the commercialization costs and gross margin for any product resulting from the collaboration that receives regulatory approval. We record our portion of the gross margin as collaboration and other revenue, and we record our portion of the commercialization costs as marketing, selling, and administrative expense. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration. Our revenue related to this collaboration (which is, to-date, entirely related to Trajenta) was \$249.2 million, \$88.6 million, and \$15.1 million for the years ended December 31, 2013, 2012, and 2011, respectively.

### Solanezumab

We have an agreement with an affiliate of TPG-Axon Capital (TPG) whereby TPG funded a portion of the Phase III development of solanezumab. Under the agreement, TPG's obligation to fund solanezumab costs was not material and ended in the first half of 2011. In exchange for their funding, TPG may receive success-based sales milestones totaling approximately \$70 million and mid-single digit royalties contingent upon the successful development of solanezumab. The royalties would be paid for approximately ten years after launch of a product.

### Baricitinib

In December 2009, we entered into a worldwide license and collaboration agreement with Incyte Corporation (Incyte) to acquire development and commercialization rights to its Janus tyrosine kinase (JAK) inhibitor compound,

now known as baricitinib, and certain follow-on compounds, for the treatment of inflammatory and autoimmune diseases. Incyte has the right to receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20 percent if the product is successfully commercialized. The agreement provides Incyte with options to co-develop these compounds on an indication-by-indication basis by funding 30 percent of the associated development costs from the initiation of a Phase IIb trial through regulatory approval in exchange for increased tiered royalties ranging up to percentages in the high twenties. In 2010, Incyte exercised its option to co-develop baricitinib in rheumatoid arthritis. The agreement also provides Incyte with an option to co-promote in the U.S. and calls for payments associated with certain development, success-based regulatory, and sales-based milestones. Upon initiation of Phase III trials for the treatment of rheumatoid arthritis in the fourth quarter of 2012, we incurred a milestone-related expense of \$50.0 million which was recorded as research and development expense. As of December 31, 2013, Incyte is eligible to receive up to \$415.0 million of additional payments from us contingent upon certain development and success-based regulatory milestones as well as an additional \$150.0 million of potential sales-based milestones.

### **Tanezumab**

In October 2013, we entered into a collaboration agreement with Pfizer Inc. (Pfizer) to jointly develop and globally commercialize tanezumab for the potential treatment of osteoarthritis pain, chronic low back pain and cancer pain. Tanezumab is currently in Phase III development and is subject to a partial clinical hold by the FDA pending submission of nonclinical data to the FDA. Under the agreement, the companies share equally the ongoing development costs and, if successful, in gross margins and commercialization expenses. Contingent upon the parties continuing in the collaboration after receipt of the FDA's response to the submission of the nonclinical data, we will be obligated to pay an upfront fee of \$200.0 million. This payment would be immediately expensed. In addition to this fee, we may pay up to \$350.0 million in success-based regulatory milestones and up to \$1.23 billion in a series of sales-based milestones, contingent upon the commercial success of tanezumab. Both parties have the right to terminate the agreement under certain circumstances.

### **Summary of Collaboration-Related Commission and Profit-Share Payments**

The aggregate amount of commission and profit-share payments included in marketing, selling, and administrative expense pursuant to the collaborations described above was \$203.7 million, \$188.5 million, and \$125.4 million for the years ended December 31, 2013, 2012, and 2011, respectively.