

VIA EDGAR

April 15, 2013

U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, NE Washington, D.C. 20549

Attention: Jim B. Rosenberg

## Re: Alexion Pharmaceuticals, Inc. Form 10-K for the Fiscal Year Ended December 31, 2012 Filed February 19, 2013 File No. 000-27756

Ladies and Gentlemen:

On behalf of Alexion Pharmaceuticals, Inc. ("Alexion"), submitted herewith is a response to comments contained in the letter dated March 25, 2013 from Mr. Jim B. Rosenberg of the Staff ("Staff") of the Securities and Exchange Commission ("Commission") to Mr. Vikas Sinha, Alexion's Executive Vice President and Chief Financial Officer. The comments and responses set forth below are keyed to the numbering of the comments and the headings used in the Staff's letter.

On behalf of Alexion, we advise you as follows:

#### <u>General</u>

1. Please note that we intend to review the Part III information that you intend to incorporate by reference into your Form 10-K when filed. We may have further comments after reviewing that information and we will not be able to clear our review of your filing until we have the opportunity to resolve any resulting comments.

**Response:** We anticipate filing our definitive proxy statement for our 2013 annual meeting of shareholders, which includes the information that will be incorporated by reference into Part III of our Form 10-K, on or about April 15, 2013 and not later than 120 days after the end of our fiscal year ended December 31, 2012. We understand that the Staff may have further comments after reviewing that information.

## Management's Discussion and Analysis of Financial Condition and Results of Operations

<u>Critical Accounting Policies and the Use of Estimates</u> <u>Revenue Recognition, page 48</u>

2. Please provide us proposed disclosure to be included in future filings which separately breaks out the current provision for rebates related to sales made in the current period from the current provision for rebates related to sales made in prior periods, or modify your disclosure to state, if true, that the adjustments to prior period estimates were immaterial to your results of operations.

**Response:** In response to the Staff's comment, we will provide in our future Annual Reports on Form 10-K disclosure in substance similar to the following:

"We have provided balances and activity in the rebates payable account for the years ended December 31, 2013, 2012 and 2011 as follows:

	Rebates Payable	
Balance at December 31, 2010	\$	4,660
Current provisions relating to sales in current year		36,045
Adjustments relating to prior years		(1,462)
Payments/credits relating to sales in current year		(15,226)
Payments/credits relating to sales in prior years		(2,271)
Balance at December 31, 2011	\$	21,746
Current provisions relating to sales in current year		80,131
Adjustments relating to prior years		(2,566)
Payments/credits relating to sales in current year		(22,634)
Payments/credits relating to sales in prior years		(14,343)
Balance at December 31, 2012	\$	62,334

# Research and Development Expenses, page 50

3. Please provide us proposed disclosure to be included in future filings showing the effect of changes in the estimate for each period presented related to your clinical trial activity expenses by CROs, or disclose that changes in this estimate were historically not material to your results of operations.

**Response:** In response to the Staff's comment, we will insert a statement in future filings that changes in the estimate were historically not material to Alexion's results of operations. If we

determine that changes in such estimate are material at a future date, our then next due filing will show the effect of changes in the estimate for each period presented. In our next filing, we expect to provide disclosure in substance similar to the last sentence of the following paragraph, which is currently included in our disclosure:

"We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CRO's), clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CRO's and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in research and development expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. The estimates may differ from the actual amount subsequently invoiced, which may result in adjustment to research and development expense several months after the related services were performed. Adjustments for prior period estimates have not had a material impact on our results of operations."

## <u>Results of Operations</u> <u>Comparison of the Year Ended December 31, 2012 to the Year Ended December 31, 2011</u> <u>Net Product Sales, page 53</u>

4. Regarding the \$350.7 million increase in net product sales, please provide us proposed disclosure to be included in future filings that separately, by geographic region, quantifies the amount of this increase due to aHUS versus PNH separately, by price and volume. Also include in your proposed disclosure the number of patients separately for aHUS and PNH as of the end of each period presented.

## **Response:**

In response to the Staff's comment, we will include in future Annual Reports on Form 10-K additional disclosure related to revenue in substance similar to the following:

"The increase in revenue for fiscal year 2012 versus 2011 was primarily due to <u>an increased volume of unit shipments, partially</u> <u>offset by a negative impact of price and foreign exchange.</u>

We also recognized \$3,300 related to an agreement reached with a payer in the second quarter of 2012 related to product shipped during 2011.

The increase in revenue of 44.8% was due to an increase in unit volume of 49.2%, offset by a negative price impact of 2.6% and a negative impact of foreign exchange of 1.9%. The increase in volume was largely due to physicians requesting Soliris therapy for additional patients, as well as reimbursement and price approvals in additional territories and reimbursement for aHUS in the United States. The negative price impact was primarily due to increased rebates in Europe, offset by a price increase in the United States.

The negative impact <u>of foreign exchange of \$14,629</u>, <u>or 1.9%</u>, for the year ended December 31, 2012 was due to changes in foreign currency exchange rates (inclusive of hedging activity) versus the U.S. dollar for the year ended December 31, 2011. The negative impact was primarily due to the Euro, offset by a positive impact of the Japanese Yen. We recorded a gain (loss) in revenue of \$12,869 and \$(6,558) related to our foreign currency cash flow hedging program, which is included in revenue from outside the United States, for the years ended December 31, 2012 and 2011, respectively."

We highlight that we reviewed our calculation related to foreign exchange impact, and we revised the 2012 foreign exchange impact to \$14,629 from the amount of \$16,566 disclosed in our Form 10-K. The difference of \$1,937, or 0.2 percent of our 2012 net product sales, is not material, and this revision had no impact on our reported net product sales or other amounts in our financial statements. We will use the updated methodology for future calculations.

In response to the Staff's request for information related to products pursuant to Regulation S-K Item 303(a)(3)(iii), we note that Soliris is a single marketed product, which is approved for the treatment of 2 disease states, Paroxysmal Nocturnal Hemoglobinuria ("PNH") and atypical Hemolytic Uremic Syndrome ("aHUS").

We believe that disclosure of Soliris results as a single marketed product, and not separately based on disease state, is meaningful for the investor due to the following:

- The drug product provided to all patients treated with Soliris is manufactured to the same specifications, and vialed and labeled in the same manner, regardless of indication.
- We use the same distribution channels and deliver Soliris to the same customers.
- We employ the same sales force to market Soliris for the treatment of patients with PNH and aHUS.
- Customers, including distributors or healthcare facilities, may order Soliris without specifying the indication for treatment, or they may use the product for different indications after delivery. Additionally, the product may be used to treat patients for diseases other than PNH or aHUS.

Accordingly, currently we disclose changes in sales related to our only product, and we will provide additional information by product if and when we begin to sell an additional product.

The Staff has also requested information related to patient numbers, and we have provided a qualitative comment on the overall change in patients. However, changes in unit volume, as included in the revised disclosure above, provide a more meaningful, reliable and precise explanation for changes in revenue.

Our qualitative assessment of the change in the number of patients being treated with Soliris is based on our estimate of the number of patients that may be treated with Soliris at any time based on revenues, and shipment and ordering data. We do not know the precise number of patients being treated with Soliris at any given time and our estimate is subject to assumptions that may turn out not to be accurate. Further, we believe that disclosure of the number of patients may not provide an accurate or meaningful correlation to revenue growth. Dosing patterns and the frequency of dosing may be different from patient to patient, such as, for instance, varying dosing patterns for pediatric and adult patients. Rates of compliance, that is, how often a patient elects to receive infusions, also vary by patient, as does the length of time that a patient is on Soliris therapy. In addition, a patient may initiate or cease therapy at various points during any given period.

We are able to track unit volumes on a shipment-by-shipment basis with a high degree of certainty, and for the reasons stated above we believe that disclosure of changes in unit volumes (or prices, to the extent material) are more precise and reliable explanations of changes in our revenues.

Notes to Consolidated Financial Statements Note 9. Commitments and Contingencies Contingent Liabilities, F-24

- 5. Please address the following related to your accounting for the change in your estimate for probable contingency liabilities that resulted in the recognition of a \$53 million "gain" on intellectual property settlement:
  - Provide us an accounting analysis supporting whether the "gain" represented a change in estimate of a loss contingency under ASC 450-20 or the derecognition of a liability under ASC 405-20-40, and why it was appropriate to recognize the "gain" in the third quarter of 2012.
  - If you believe the "gain" represented a change in estimate of a loss contingency under ASC 450, tell us why you characterized it as a gain on the face of the consolidated statements of operations.
  - If you consider the "gain" to be a derecognition under ASC 405-20-40, tell us why recognition in the third quarter of 2012 was appropriate when the settlement occurred in the fourth quarter of 2012.

**Response:** We applied ASC450-20 to the transaction referenced in your comment, and we will provide disclosure in substance similar to the following in future filings:

"As stated in our filings with the SEC, we are aware of broad patents owned by third parties relating to the manufacture, use and sale of recombinant humanized antibodies, recombinant human antibodies, and recombinant human single chain antibodies. We have received notices from the owners of some of these patents claiming that such patents may be infringed by the development and commercialization of Soliris. Under the guidance of ASC 450, *Contingencies*, we record a royalty accrual based on our best estimate of the fair value percent of net sales of Soliris that we could be required to pay the owners of such patents under a license agreement.

In the third quarter, negotiations entered into a final phase and in October 2012, we executed a settlement and non-exclusive license agreement with a third party related to the third party's intellectual property. As a result of these negotiations and finalization of our agreement, we reduced our estimate for probable contingent liabilities as of September 30, 2012 to reflect the actual, negotiated royalty rate.

This change in estimate resulted in a positive impact in cost of sales of \$53.4 million during the third quarter 2012."

Additionally, in future filings, we will replace the reference to a "gain" with "change in estimate of contingent liability."

Should you have any questions or require additional information, please telephone the undersigned at (203) 271-8336.

Very truly yours,

/s/ Michael V. Greco

Michael V. Greco Associate General Counsel and Corporate Secretary

cc: Leonard Bell, Alexion Pharmaceuticals, Inc. Vikas Sinha, Alexion Pharmaceuticals, Inc.

John Moriarty, Alexion Pharmaceuticals, Inc. Scott Phillips, Alexion Pharmaceuticals, Inc. Patrick O'Brien, Ropes and Gray LLP