www.pwc.com

Stay informed: 2013 SEC comment letter trends

Pharmaceutical & Life Sciences industry current developments in SEC reporting

October 2013

pwc

October 2013

Clients and friends:

As year-end rapidly approaches, it is time to plan for your annual financial statement reporting. With uncertainties in the economic and regulatory environment continuing to drive increased attention on the preparation of annual reports, it is important to understand the SEC staff's greatest areas of focus.

To help you prepare for your annual reporting, PwC's Pharmaceutical & Life Sciences Industry Group has developed the enclosed publication titled *Stay informed: 2013 SEC comment letter trends*. We have compiled and analyzed the SEC staff's comment letters issued over the past few years to registrants across different sectors within the pharmaceutical and life sciences industry, including: pharmaceuticals, biotech, medical devices, pharmacy benefit management and wholesale distributors, and clinical research organizations. We have identified the areas where registrants received the majority of comments and provided sample comments along with highlights surrounding current hot topics. Also included is a discussion of other notable trends related to topics that are specific to the pharmaceutical and life sciences industry as well as historically recurring themes across other industries.

Our goal in providing this publication is to give you information to ease your stress during the upcoming financial reporting season. Further, we hope you find the insights and examples in this report to be both informative and useful as you navigate your year-end reporting process. Please feel free to contact your PwC engagement team or me to discuss the information in this publication or to address any questions you may have.

Best regards,

Karen C. Young

US Pharmaceutical & Life Sciences Assurance Leader

PricewaterhouseCoopers LLP, 400 Campus Drive, P.O. Box 988, Florham Park, NJ 07932
T: (973) 236 4000, F: (973) 236 5000, www.pwc.com/us

Table of contents


Pt
125 mL
d = 1.022 g/mL
Lot: F2-PT01123

What's new at the SEC

During the last few months, the Securities and Exchange Commission (SEC) was home to several leadership changes, confirmations and nominations. These changes primarily were associated with Mary Shapiro stepping down as SEC chair in December 2012 and the US Senate's nomination (in February 2013) and confirmation (in April 2013) of Mary Jo White, former US attorney for the Southern District of New York, as new SEC chair.

In August 2013, the Senate confirmed White as chair of the SEC through June 2019 for her second term and also confirmed Michael Piwowar and Kara Stein as SEC commissioners, filling the seats of Troy Paredes and Elisse Walter, respectively.

White's confirmation has not affected the agency's priorities—the SEC continues to focus on the implementation of Dodd-Frank and the JOBS Act and emphasizes the importance of corporate governance. Enforcement of securities law violations is also at the top of the SEC's agenda. Going forward, the SEC is revising its "neither admit nor deny" settlement practice and will seek to obtain admissions from defendants in certain limited instances. To date, the SEC has agreed to a settlement in one hedge fund adviser case that included an admission of wrongdoing. Recently, White has said that the SEC will also commit more resources to investigating accounting and financial fraud.

Hence, in July 2013, the SEC announced the creation of three new task forces: (i) Financial Reporting and Audit, established mainly to review restatements and revisions and analyze industry trends; (ii) Microcap Fraud, established mainly to investigate fraud in the issuance, marketing, and trading of microcap SEC securities; and (iii) Center for Risk and Quantitative Analytics, established mainly to support and coordinate risk identification and data analytics.

Now that the SEC's five commissioners are confirmed and its priorities aligned, it is completing the pending rulemaking with a continued emphasis on enforcement action.

Overview

To help registrants gain insight into the SEC's current areas of interest, PwC analyzed comments issued and released by the SEC staff between Jan. 1, 2011 and Aug. 15, 2013 to domestic and foreign registrants within the pharmaceutical and life sciences industry. From this analysis, we identified trends for "hot topic" areas, including industry-specific considerations and some other notable trends in comments received across industries that we believe are relevant and may be of continuous focus in the near future. For foreign registrants, this analysis included trends specific to both International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and United States Generally Accepted Accounting Principles (US GAAP). For the purpose of this analysis, all US GAAP comments from domestic and foreign registrants were analyzed together.

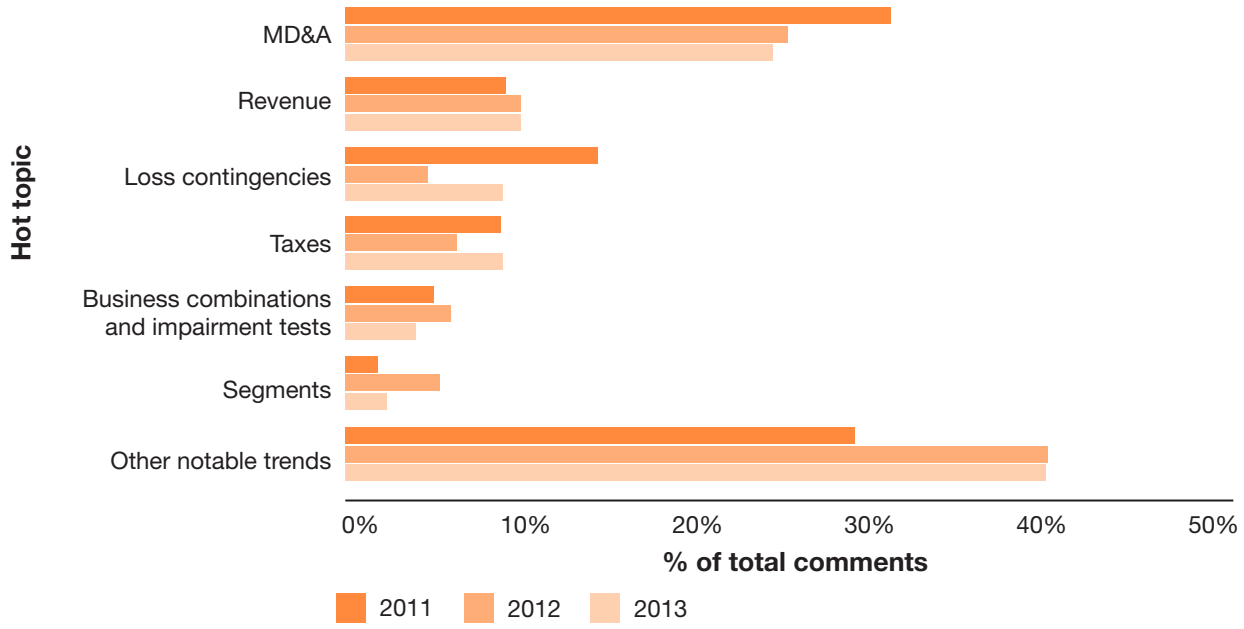
The following chart summarizes the topics identified and is inclusive of both US GAAP and IFRS comments.

Rank	"Hot topic" areas	#	%
Hot Topics			
1.	Management's discussion and analysis	297	30
2.	Revenue recognition	102	10
3.	Loss contingencies	98	9
4.	Taxes	78	7
5.	Business combinations and impairment tests	54	5
6.	Segment reporting	36	3
7.	Other notable trends:		
	10-K and 10-Q Compliance	71	7
	Operations of locations identified as state sponsors of terrorism	24	2
	Non-GAAP measures	22	2
	Other comments	260	25
	Total	**1042**	**100**

IFRS hot topics are included in this table, but are presented separately for presentation purposes

The hot topics identified in the pharmaceutical and life sciences industry are somewhat consistent with those in other industries, with Management's Discussion and Analysis (MD&A) disclosures regarding results of operations and liquidity being the most prevalent. Specific industry comments relate to product sales, research and development (R&D) and patents, among other areas. Revenue recognition also features prominently with comments specific to the industry regarding revenue milestones and collaboration agreements. Loss contingencies, another recurring topic, reflect a significant trend in the pharmaceutical and life sciences industry including comments regarding litigation and the US Food and Drug Administration (FDA) warning letters. The other relevant areas are not necessarily industry-specific but clearly were significant in recent years and included comments on taxes, business combinations and impairment tests, and segment reporting.

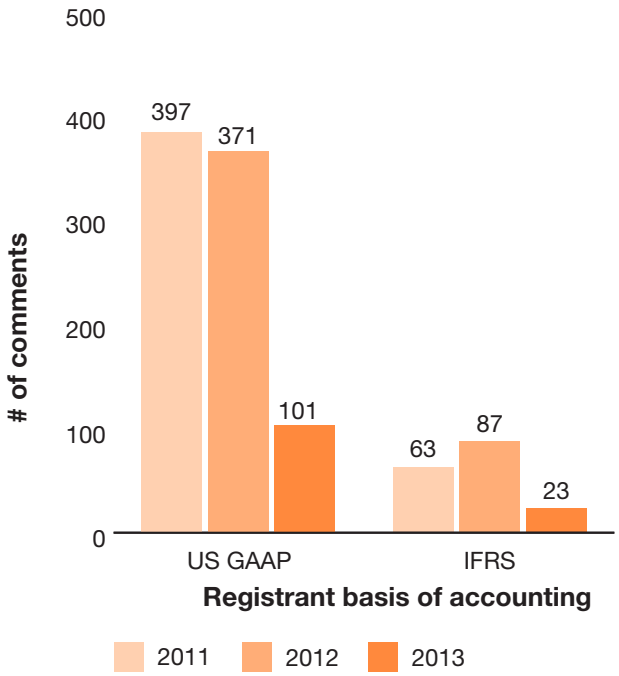
Hot topics as % of total comments by year of comment letter



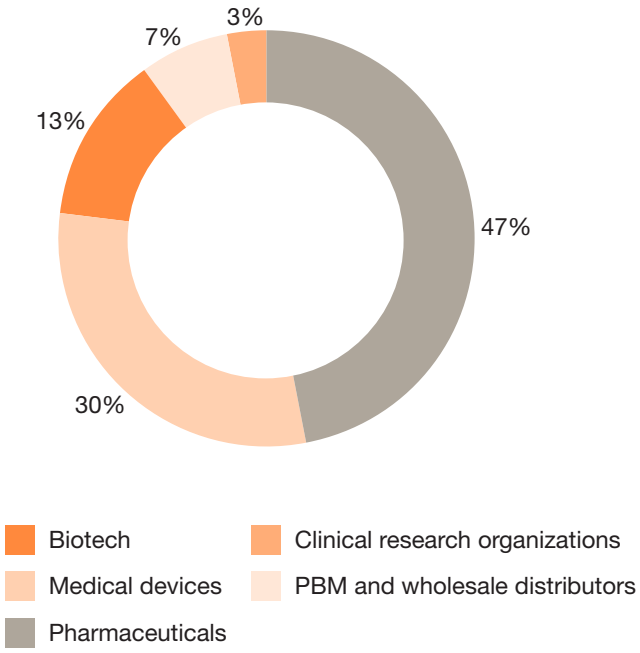
The hot topic areas remained consistent throughout the period of our analysis. The volume of comments for 2013 is affected by the cut-off date considered when preparing this publication. In terms of the number of comments, we analyzed 1042 comments, including 869 from registrants that file in accordance with US GAAP and 173 from registrants that file in accordance with IFRS.

Our analysis considered the breakdown of the pharmaceutical & life sciences industry into five sectors: pharmaceuticals, medical devices, biotech, pharmacy benefit management (PBM) and wholesale distributors, and clinical research organizations. In terms of the aforementioned hot topic areas, all five of the sectors, when analyzed individually, presented substantially similar trends.

Registrant basis of accounting—
# of comments by year of comment letter



Breakdown by sector



Methodology

For both domestic and foreign registrants reporting under US GAAP, the analysis of SEC staff comment letter trends was based on comments issued and released by the SEC between Jan. 1, 2011 and Aug. 15, 2013 and comprised of Forms 10-K, 10-Q and 20-F. For consistency of evaluation, the analysis was based solely on the SIC codes indicated on the SEC EDGAR website for each respective registrant. The population was analyzed by pharmaceutical and life sciences sectors and determined by the following SIC codes:

- Pharmaceuticals (registrants with revenue above $1 billion) – 2834 and 2835
- Medical Devices (registrants with revenue above $500 million) – 3826, 3827, 3841, 3842, 3843, 3844, 3845 and 3851
- Biotech – 2836
- PBM and Wholesale Distributors – 5122 and 5912
- Clinical Research Organizations – 8731

For IFRS pharmaceutical & life sciences registrants, the analysis of SEC staff comment letter trends was based on comments issued and released by the SEC between Jan. 1, 2011 and Aug. 15, 2013 and comprised all filings in accordance with IFRS. Results included comments issued for 20-F, 10-Q, 20FR12B, 40-F, 6-K, and Draft Registration Statements (DRS). For consistency of evaluation, the analysis was based solely on the SIC codes indicated on the SEC EDGAR website for each respective registrant. No revenue metrics were specified in the criteria for this search. The population was analyzed by pharmaceutical and life sciences sectors and determined by the following SIC codes:

- Pharmaceuticals – 2834 and 2835
- Medical Devices – 3826, 3827, 3841, 3842, 3843, 3844, 3845 and 3851
- Biotech – 2836
- PBM and Wholesale Distributors – 5122 and 5912
- Clinical Research Organizations – 8731

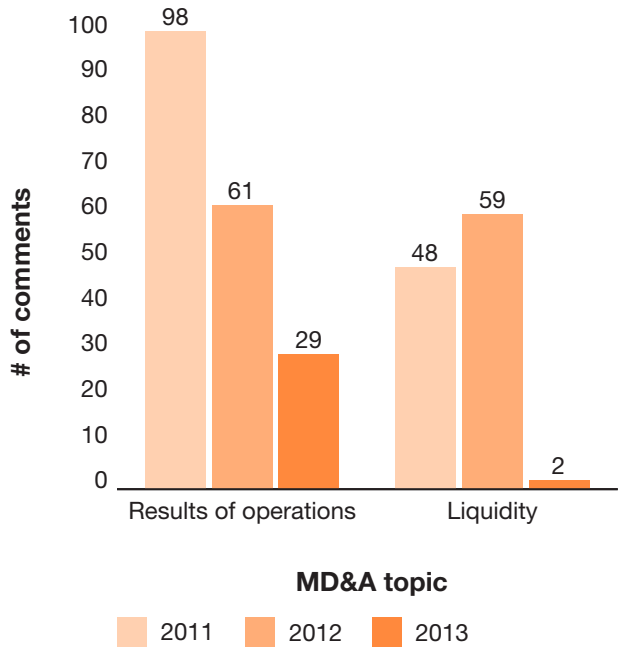
Management's discussion and analysis

MD&A continues to be one of the top areas for comments by the SEC. The purpose of MD&A is "to give investors an opportunity to look at the registrant through the eyes of management by providing a historical and prospective analysis of the registrant's financial condition and results of operations, with particular emphasis on the registrant's prospects for the future."[1]

The guidance set forth in Regulation S-K, Item 303 identifies five categories of disclosure — results of operations, liquidity, capital resources, off-balance sheet arrangements and tabular disclosure of contractual obligations — along with the requirements for each. The SEC staff comments on MD&A are primarily focused on results of operations and liquidity disclosures.

In the following sections we have analyzed SEC staff comments by component of MD&A.

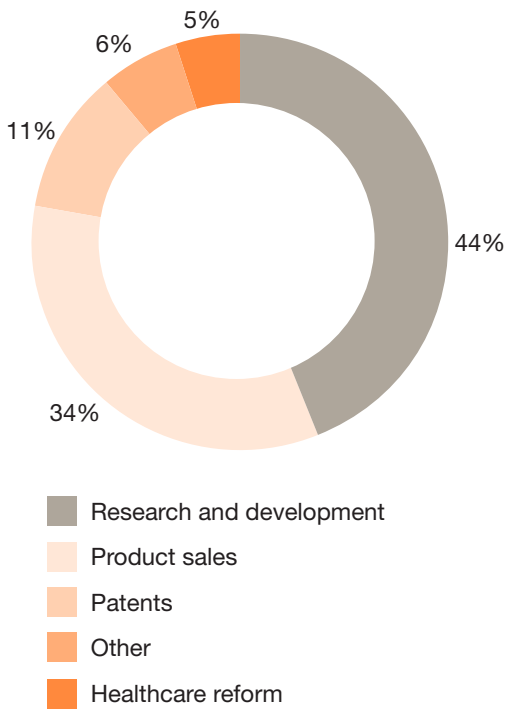
# of comments by MD&A subtopic by comment letter year



Results of operations

The majority of comments related to MD&A focus on the results of operations section. The chart below shows a breakdown of SEC staff comments on results of operations by specific subtopics.

MD&A results of operations topics



1 SEC Financial Reporting Release 36

Research and development

Pharmaceutical, medical device and biotech companies incur a significant amount of R&D expenses. The SEC staff has indicated that the MD&A discussion for R&D expenditures often is not as informative as it could be. For that reason, the SEC staff believes that certain information (e.g., completion dates, completion costs, etc.) about the status of major research projects should be discussed and disclosed.

Compliance with Accounting Standard Codification (ASC) 730, *Research and Development*, is another area of focus. The SEC staff has requested that registrants discuss what indirect costs are allocated to R&D to ensure compliance with ASC 730-10-25. In accordance with this guidance, R&D costs shall include a reasonable allocation of indirect costs. General and administrative costs that are not clearly related to R&D activities shall not be included as R&D costs.

Sample comments

(1) For each of your research and development projects discussed on pages xx through xx that are individually material, please provide us proposed disclosure to be included in future periodic filings as follows:

- The costs incurred during each period presented and to date on the project;
- The nature of efforts and steps necessary to complete the project;
- The risks and uncertainties associated with completing development;
- The extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project; and
- Where a future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency, or approval from a regulatory agency can be reliably determined, disclosure should be made.

(2) You discuss some of your specific pipeline projects on pages xx through xx. Please provide us the following information:

- The composition of the total research and development expense shown in the financial statements for each period presented, as practicable. This may take a variety of forms depending on how you manage and report projects within the organization. We believe distinguishing between preclinical and clinical development categories and further by late stage such as phase III development categories along with providing the number of projects in each category helps provide information necessary to understand the pipeline and trends. To the extent that management has information available by therapeutic class, we believe that further enhances the understanding of research and development expense and trends.
- If the future research and development expense or composition of research and development expense is reasonably likely to differ from current trends, provide us proposed disclosure to be included in future periodic reports discussing the reasons for the change and the expected effect on future operations and financial position.

(3) In the last paragraph on page xx you indicate that research and development expenses include proportionate allocations of enterprise-wide costs. Please tell us the types of enterprise-wide costs that you allocate to research and development expense and the bases you use to allocate them. Also, tell us the amount of these enterprise-wide costs allocated to research and development expenses in each of the last three years. In your response, please clarify how these costs are clearly related to research and development activities and how your allocation is reasonable under ASC 730-10-25-2e.


רכוש רותם תעשיות בע"מ
מק"ט : 2723

Product sales

Item 303(a)(3) of Regulation S-K contains the requirements for registrants to discuss results of operations in MD&A. Additional guidance on MD&A is contained in Financial Reporting Release (FRR) 36 and FRR 72. Registrants should ensure that the results of operations discussion in MD&A provides readers with a sufficient understanding of the significant components of revenues and expenses that, in management's judgment, facilitate an understanding of the registrant's results of operations. In addition to the description of the significant components of changes in historical periods, registrants should describe any known trends or uncertainties that are expected to have a material favorable or unfavorable impact on revenues or income from continuing operations.

Most pharmaceutical and medical device companies have significant product sales allowances primarily relating to various rebate programs that are offered to their customers. The SEC staff has requested registrants to further enhance their disclosures regarding these allowances that reduce gross sales by providing a roll-forward of these allowances year over year for each material product sales allowance.

Sample comments

(1) We note that your fiscal year 20XX revenues increased approximately xx% as compared to 20XX and also note that your discussions herein and by operating segment on page xx repeatedly indicate that the increase in 20XX revenues "reflects strong growth in most product categories." In light of the significant increase in your 20XX revenues, your Management's Discussion and Analysis disclosure appears broad and does not provide a thorough enough analysis to give readers a view of the company through the eyes of management. In future filings, please quantify each material factor underlying the changes in your revenues, including price changes and volume changes by type of product. Disclose separately the effect on operations attributable to each factor causing the aggregate change from year to year and disclose the nature of, or reason for, each factor causing the aggregate change. Your future disclosures should reveal underlying material causes of the factors described and any known or expected future impact on operating results. Please also incorporate the above comment to all disclosures in the analysis of your results of operations in Management's Discussion and Analysis, including changes in operating expenses during the periods presented. For further guidance, please refer to Item 303 and the related instructions in Regulations S-K as well as SEC Interpretive Release No. 33-8350.

(2) We note that your spine surgery product revenues increased $xx.x million and your biologics revenues increased $x.x million in 20XX compared to 20XX. Please respond to the following:

1. Please separately quantify the impact of volume changes on your spine surgery and biologics revenue. We note your disclosure that price changes were not material.
2. Please quantify the amount of foreign sales in each period presented.
3. Please explain the nature of any other significant changes in your revenue and quantify those changes to the extent possible, such as changes due to acquisitions, foreign currency movements, etc. Your response should include the reasons for significant changes in your biologics revenue.

In this regard, please explain how you considered Item 303 and the related instructions in Regulation S-K, SEC Interpretive Release No. 33-8350 (FRR No. 72), and SAB Topic 13.B.

(3) We see that throughout MD&A, you attribute fluctuations in net sales to changes in "product mix", increases /decrease in demand for products. In future filings please include sufficient disclosures about the specific reasons for fluctuations in net sales and, to the extent material to an understanding of your financial statements and other disclosure, an analysis of any trends or changes in demand in certain geographic locations. Consider disclosing whether these changes represent any known trends or uncertainties that could have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. Please refer to Item 303(A)(3) of Regulation S-K and Financial Reporting Release No. 33-8350.

(4) Please provide proposed disclosure to be included in future periodic filings to explain how much of the change in your revenues involves increases for new products launched in the current year and decreases for products launched in prior years. In addition, provide proposed disclosure to quantify the effect that volume and price variances had on your revenue for each year presented.

(5) We believe that your disclosure related to estimates of product sales allowances that reduce gross revenue could be improved. Please provide us proposed disclosure to be included in future periodic filings that includes a roll forward for each product sales allowance accounts for each period presented showing the following:

1. Beginning balance,
2. Current provision related to sales made in current period,
3. Current provision related to sales made in prior periods,
4. Actual returns or credits in current period related to sales made in current period,
5. Actual returns or credits in current period related to sales made in prior periods, and
6. Ending balance.

If you are unable to provide the above-noted roll forwards, please quantify the amount of changes in prior period estimates recorded in each period presented or explicitly state that there were no material changes in estimates, if true.

(6) 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.

Patents

Pharmaceutical companies often maintain that patent protection for drugs ensures they are able to invest billions of dollars into the development of new products, with the ability to take advantage of drug sales for an extended period of time. Patents are a significant part of investments in R&D activities and extremely important for the industry. As a result, the SEC staff has requested that registrants enhance their disclosures and make a clearer distinction between their product rights (including licenses and patents) and the revenues that are generated from these rights, as well as the expiration dates of product rights to better explain the potential impacts in the financial statements.

Sample comments

(1) In order to better understand the connection between your product rights including licenses and patents and the revenues that are generated as a result of these rights, as well as to assess the potential for impairment, please provide us a break out of revenues by product or the level disclosed in your earnings press releases, the name or description of the related product rights including licenses and patents, the value assigned, and the expiration date(s) of the product rights in a format to be included in your future periodic filings.

(2) We note "several significant licenses or exclusivity rights expire at various times during the next 15 years." To the extent the licenses and patents referred to in the discussions are material, please provide us proposed revised disclosure for inclusion in future filings that expands the respective discussions to identify the products and/or technology to which the license, patent or group of patents pertain, and disclose when the respective license, granted patent or groups of patents are scheduled to expire.

(3) Your disclosure on page xx and elsewhere indicates that you are losing patent exclusivity in 20XX and 20XX on products that account for a significant amount of your revenue. Please provide us proposed disclosure to be included in future periodic reports that quantifies the expected effect of these patent expirations on your financial position, results of operations and capital resources.

Healthcare reform

The Healthcare Reform Act required many changes for the pharmaceutical and life sciences industry, including an annual fee on pharmaceutical manufacturers, changes in Medicaid prescription drug rebates, changes in the Medicare coverage gap, a new medical device excise tax, as well as other changes that may have affected current and future results of operations. The SEC staff has requested registrants to provide proposed disclosure to be included in future periodic reports of their accounting policies for these changes. For example, the SEC staff has requested disclosure on how registrants are recording the amounts due for the fee assessed to pharmaceuticals and where the amounts are classified in the income statement. In addition, they have asked registrants to provide proposed disclosure to be included in future periodic reports reflecting the effects the Healthcare Reform Act had on their liquidity and results of operations for each period presented. They have also requested participants to disclose the anticipated effects the legislation will have on future liquidity and results of operations. SEC staff has requested registrants to provide revised disclosures quantifying material impacts.

The Healthcare Reform Act imposed a tax equal to 2.3% of the sales price of any taxable medical device by a medical device manufacturer, producer or importer. The excise tax applies only to sales occurring after Dec. 31, 2012. Since the medical device tax is new, it is an emerging subject of SEC staff comment letters.

Sample comments

(1) On page xx, you describe certain provisions of Health Reform Laws that could have a material adverse effect on your business, financial position and results of operations, such as the assessment of a pharmaceutical manufacturer fee and an increase in rebates paid by manufacturers under Medicaid programs. Please provide us proposed disclosure to be included in future periodic filings the describes and quantifies the effects of the Health Reform Laws on your liquidity and results of operations and the effects this legislation are expected to have on your future liquidity and results of operations. For example, include the following information.

- In 20XX and 20XX, the amount incurred related to the increase in the Medicaid rebate;
- In 20XX, the amount incurred related to Medicare Part D 'donut hole'; and
- The expected effect in 20XX and beyond.

Also, provide us corresponding accounting policy disclosures to be included in your financial statements in future periodic reports.

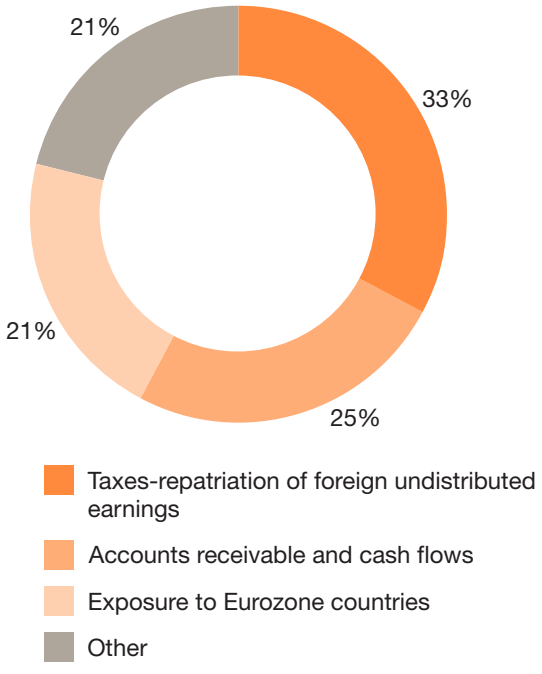
(2) Although you disclose the aspects of health care reform legislation that affect the company, you do not quantify its impact on your financial statements. In this regard, please provide us proposed revised disclosure to be included in future periodic reports indicating the amount of the reduction to revenues for the increased Medicaid rebate in 20XX and 20XX and for additional rebate associated with the Medicare Part D "donut hole" in 20XX. Also, include in your proposed revised disclosure the amount of the branded prescription drug fee you recorded in your statement of earnings in 20XX, in which line item it is classified therein and highlight that this fee is not tax deductible. Finally, if you believe that the expected effects of health care reform legislation in 20XX and beyond will be materially different than the 20XX trends, include the expected effects in the proposed revised disclosure.

(3) The Healthcare Reform Act requires many changes for the pharmaceutical industry, including an annual fee to be assessed on pharmaceutical manufacturers, changes in Medicaid prescription drug rebates, changes in the Medicare coverage gap, as well as other changes that may have affected your current results of operations. In addition, other changes may affect future periods. Please provide proposed disclosure to be included in future periodic reports of your accounting policies for the changes. For example, disclose how you are recording the amounts due for the fee assessed to pharmaceuticals and where the amounts are classified in the income statement. Provide us your accounting basis for the policies to be disclosed. In addition, provide proposed disclosure to be included in future periodic reports for Management's Discussion and Analysis of the effects the Healthcare Reform Act had on your liquidity and results of operations for each period presented and the anticipated effects the legislation will have on your future liquidity and results of operations.

Liquidity

Liquidity disclosures continue to be an area of focus within MD&A. As a result of lingering economic crises and weak recoveries in the United States and abroad, we expect the SEC staff to continue its focus on liquidity. Comments received by registrants in the industry indicate that the SEC staff expects robust and transparent discussion of liquidity, including anticipating uncertainties, commitments, material covenants and the likelihood of non-compliance and demands that could have an impact on liquidity. Preparers of MD&A should ensure that a robust and transparent discussion of these matters is embedded within their liquidity section. Specific areas of focus within the liquidity section of the MD&A included repatriation of foreign undistributed earnings disclosures, accounts receivable and cash flows, and exposure to Eurozone countries among other, less representative areas. The chart below shows a breakdown of SEC staff comments by topic.

MD&A liquidity topics



Taxes—repatriation of foreign undistributed earnings

Within the area of income taxes, the indefinite reinvestment assertion continues to be a recurring topic in regards to MD&A and liquidity. Registrants asserting indefinite reinvestment are being asked to expand their financial statements and MD&A disclosures to more clearly describe how the geographic location of cash in different jurisdictions impacts the registrant's liquidity position. The SEC staff continues to issue comment letters asking registrants to disclose in more detail the relationships and the nature of the investments and the factors considered in concluding that such investments in foreign subsidiaries are essentially indefinite in duration. SEC staff comment letters have also focused on asking registrants to elaborate on what the specific plans are for use of the cash in the various jurisdictions (e.g., CapEx, plant expansion, etc.) that supports the indefinite reinvestment assertion. The disclosure is intended to highlight the possibility that cash may be currently unavailable to fund domestic operations or obligations without paying a significant amount of taxes upon repatriation, and the expected effect on registrants' liquidity and capital resources.

Sample comments

(1) You disclose that the $x.x billion decrease in cash, cash equivalents and marketable securities and investments is primarily due to your acquisition of [Company] and to your common stock repurchase program offset by cash generated by operating activities. As a result of these activities, your cash, cash equivalents and marketable securities held domestically declined from $x.xxx billion or xx% of the consolidated total at March 31, 20XX to $xxx million or xx% of your consolidated total at December 31, 20XX. Although you disclose that you believe that current cash levels, coupled with funds to be generated by ongoing operations, will continue to provide adequate liquidity to support operations and to facilitate potential acquisitions of products, payments of achieved milestones, capital investments and continued share repurchases, you do not appear to discuss the potential impact of a mismatch in resources and obligations from a domestic versus foreign operations perspective. Please provide us proposed revised disclosure to be included in future periodic report that highlights the implications of repatriating any of the $x.x billion in undistributed foreign earnings identified in Note xx on page xx of your March 31, 20XX Form 10-K.

(2) Refer to the "net benefit on repatriated earnings" in your reconciliation of the statutory tax rate to the effective tax rate. Please explain to us the nature of this item and the factors that you considered in concluding that your investments in foreign subsidiaries are essentially permanent in duration.

(3) We note from Note xx to the financial statements the amount of pre-tax foreign income and your policy of indefinitely reinvesting the earnings of your foreign subsidiaries. To the extent such amounts could be considered material to an understanding of your liquidity and capital resources, please revise your future filings to disclose the amounts of the cash and investment amounts held by your foreign subsidiaries that would not be available for use in the United States. Further, please provide a discussion of any known trends, demands or uncertainties as a result of this policy that are reasonably likely to have a material effect on the business as a whole or that may be relevant to your financial flexibility. Refer to Item 303(a)(1) of Regulation S-K, SEC Release 33-8350, and Financial Reporting Codification Section 501.03.a.

Accounts receivable and cash flow discussions

Cash flow considerations such as those related to accounts receivable, including the determination of allowances for doubtful accounts, are usually an important part of MD&A liquidity discussions. Disclosures on how the estimates were determined and the expected impact of past due balances on registrants' cash flow are key factors in the assessment of liquidity. The SEC staff has asked registrants to enhance their disclosures to fully explain significant changes in accounts receivables and how aging analysis was applied to the receivable provisions. Additional consideration on why registrants believe overdue receivables will be collected was also an area of interest. The SEC staff comments ultimately ask registrants to provide more robust disclosures addressing how the accounts receivable were assessed.

Sample comments:

(1) You state here "A number of new products were launched in the year ended March 31, 20XX, which required significant cash outflows. As a result of increased accounts receivable and inventory from these launches, our working capital balance increased during such period, but the resulting cash inflows were not fully realized during such period." Please provide us proposed disclosure to be included in future periodic reports that more fully explains why accounts receivable increased at a greater rate than sales resulting in an increase in days' sales in accounts receivable from 66 days at March 31, 20XX to 79 days at March 31, 20XX (based on the most recent quarter's sales).

(2) From your response to comment x in your response letter, we see that for sales to public or government hospitals, you do not make any accounts receivable provisions based on aging because you have no record of default from that category of customers. Please clarify for us whether the public and government hospitals to which you refer are located solely in China, or tell us the other countries where you sell to that category of customers and explain your conclusion that credit risk in those countries is also minimal.

(3) Please refer to your response to prior comment x. In light of your extended payment arrangements, long outstanding account receivables and related allowances for losses, please revise future discussions in critical accounting policies to include a quantified, summarized table of the aging of your accounts receivable and allocation of reserves to the aging buckets similar to the 'Total' section on page xx of your letter.

(4) We also note that your accounts receivable allowance, as disclosed on page xx, has remained relatively unchanged. In addition, on page xx you disclose that the age of receivables is one of the two primary factors in determining the allowance for doubtful accounts. Describe for us in greater detail your accounting policy and process for establishing the allowance for doubtful accounts and identifying accounts receivable balances at risk for non-payment, including how any longer credit terms provided to international customers impacted the analysis. Explain how your policy considered the guidance in ASC 310-10-35-5 through 35-11. Tell us whether you ever extend the credit repayment periods for customers and if so, describe to us the circumstances under which you would normally provide these extensions and whether the arrangements were formally documented or verbal in nature. Provide us with an aging of your accounts receivable balances as of December 31, 20XX and March 31, 20XX, highlighting for us any account balances that were 60 days, 90 days, 180 days, 360 days and 720 days past due at those dates.

Exposures to Eurozone countries

Because of past uncertainties about European sovereign debt holdings and concerns about the direct and indirect exposures risks to Eurozone countries, in early 2011 the SEC staff issued the Corporate Finance Disclosure Guidance: Topic No. 4 – European Sovereign Debt Exposures.

This guidance was provided in response to needs identified during the SEC staff comment process. As part of this process, registrants enhanced their disclosures of exposures to sovereign debt in several countries after an initial round of comments; however, SEC staff still found that expanded and enhanced disclosures were not yet consistent from registrant to registrant and determined that investors would benefit from better and more consistent disclosures.

The uncertainty in the Eurozone has also increased the importance of transparent disclosure for the pharmaceutical and life sciences industry. Registrants have received comments on their European disclosures, and the ongoing economic instability in those territories continues to draw the attention of the SEC staff. Specifically, comment letters have focused on the extent of, and level of disaggregation in, the disclosures with respect to the registrants' exposures in those affected territories.

Sample comments

(1) You indicate that there have been customers in Southern Europe for which days outstanding has increased while payment is pursued. Please tell us the total amount due and the amount past due from these customers by customer and by country. Indicate those customers that are "partially or directly funded by government institutions."

(2) You discuss the issue of increasing past due receivables from product sales to government- owned or supported customers in Greece, Italy, Portugal and Spain. You state that over $x billion is outstanding at March 31, 20XX and that $xxx.x million was more than 120 days past due based on contractual payment terms, and in your discussion of working capital as of March 31, 20XX, you state that the increase of $xxx.x million in accounts receivable, net, was primarily driven by slower collections in southern European countries. With respect to these customers in Greece, Italy, Portugal and Spain, please address the following:

- Provide us an expansion of the 120 day past due receivables into more precise aging buckets such as over six, nine and twelve months showing the amounts due from each customer.
- In your critical accounting policies, estimates and judgments for your allowance for doubtful accounts in your December 31, 20XX Form 10-K, you disclose that your allowance for doubtful accounts balance as a percentage of total accounts receivable did not materially change from December 31, 20XX to December 31, 20XX, and you disclose, in your MD&A discussion of SG&A, that bad debt expense increased only $x.x million for the three months ended March 31, 20XX. It does not, therefore, appear that you have significantly increased your allowance for doubtful accounts for the increase in the aging of these receivables. Please tell us the amount of your allowance for doubtful accounts at March 31, 20XX, the amount reserved for these customers in Greece, Italy, Portugal and Spain, and the basis for your conclusion that your allowance for doubtful accounts adequately addressed the collectability of current and past due receivables from these customers at March 31, 20XX.
- Describe for us management's plans and options available to collect the past due receivables and the expected effects of these customers on your future financial position and results of operations including reduction in sales to the customers.

(3) We note that as a result of providing extended or delayed payment plans in Europe, your receivables to customers in those countries increased during the ended December 31, 20XX. Additionally, we note your disclosure that you are engaging in a more robust risk assessment for these customers. Please revise future filings to summarize the additional procedures you are undertaking to evaluate the risks and collectability of these receivables.

(4) Please refer to your response to comment x. Please provide proposed additional disclosure to be included in future filings that includes an aging of your sovereign and non-sovereign receivables related to Italy, Spain and Greece along with the allowance recorded by category. We believe that the information should be broken down by any country which is experiencing significant economic, fiscal and/or political strains such that the likelihood of default would be higher than would be anticipated when such factors do not exist. In this respect, separately disclose your receivable balance for Italy, Spain, and Greece. Also, please consider CF Disclosure guidance Topic 4 in your proposed disclosure which can be found at http://sec.gov/divisions/corpfin/guidance/cfguidance-topic4.htm.

Revenue recognition

Multiple element arrangements

SEC staff comments in this area primarily focus on robust disclosures of a company's accounting treatment for multiple element arrangements in accordance with ASC 605, *Revenue Recognition*. The SEC staff has requested registrants to disclose the nature of the arrangement, the significant deliverables, as well as a discussion of the significant factors, inputs, assumptions, and methods used to determine selling price (e.g., whether vendor-specific objective evidence, third-party evidence, or estimated selling price) for the significant deliverables. Registrants also must disclose whether the deliverables in the arrangements qualify as separate units of accounting, or must disclose the reasons that they do not qualify as separate units of accounting.

SEC staff comments also focus on a company's accounting policy as well as a company's evaluation of the delivered licenses, and whether or not that license has stand-alone value.

Also, arrangements that have multiple deliverables require a gross-versus-net assessment for each unit of account, in accordance with ASC 605-45-45. "Gross versus net" continues to be a challenging area. The accounting guidance provides indicators to help identify the principal party, who will recognize revenue on a gross basis (the amount billed to the customer) and the party that is the agent, who will recognize net revenue (the amount billed to the customer less the amount paid to a supplier). For example, medical device companies selling instruments along with an extended warranty to a customer may need to consider the relevance of such guidance. In some cases, the medical device company might be the principal for the product sale. However, if another party services the extended warranty, the medical device company could be an agent, and therefore, recognize revenue on a net basis, for that portion of the arrangement.

Furthermore, the SEC staff has asked registrants to disclose royalty ranges for significant licensing arrangements that they are entitled to receive, where applicable. The SEC staff has stated that this type of information is important to investors. However, if registrants prefer confidential treatment for specific agreements, they need only to disclose a range of royalties rather than the actual royalty percentage.

Sample comments

(1) We reference the disclosure that you account for your XX agreements under the accounting guidance for revenue arrangements with multiple deliverables. Please tell us specifically how you apply FASB ASC 605-25-25-30 in your accounting for XX agreements, including how you allocate consideration at the inception of the arrangement to all deliverables. In future filings please also include the applicable disclosures required by FASB ASC 605-25-50. Please show us your proposed revised disclosure.

(2) You indicate that as part of the agreement with [Company], you have committed to certain continued development and manufacturing activities with these two companies. Please tell us more information about the nature and extent of these obligations and your accounting treatment for them. Please tell what consideration was given to the application of ASC 605-25 to this agreement that has multiple deliverables (i.e. business, development services, and manufacturing services) in determining separate units of accounting and measuring and allocating the arrangement consideration.

(3) We note from your disclosures that you sell multiple products and services and that some of the services you sell are performed by other parties. Please expand your disclosures to describe your typical revenue model and the indicators you evaluated, in accordance with ASC 605-45-45, to report revenue on a gross basis.

(4) For your license agreements with [Company A] and [Company B]:

1. Upfront payments;
2. Aggregate potential milestone payments;
3. Percentage royalty payments;
4. Termination provisions; and,
5. Duration;

Note that where you have received confidential treatment for specific royalty percentages, we are only requesting disclosure of the range of royalties not the actual royalty percentage. Where applicable, please ensure the percentage range of royalties presented is within ten percentage points (e.g., "single digits," "between 10 percent and 20 percent," or "in the twenties").

Milestone method of revenue recognition

For each arrangement that includes milestone consideration accounted for under ASC 605-28, *Milestone Method of Revenue Recognition*, the disclosure guidance in ASC 605-28-50 should be followed. This guidance requires a registrant to disclose, in the notes to the financial statements, a description of the overall arrangement, a description of each milestone and related contingent consideration, a determination of whether each milestone is considered substantive, the factors that the registrant considered in determining whether the milestone or milestones are substantive and the amount of consideration recognized during the period for the milestone or milestones.

While ASC 605-28-50 states that a company should disclose each milestone, the SEC staff has permitted registrants, in certain circumstances, to group milestones by major category or type (e.g., stage of development, commercial, regulatory). Rather than disclosing each milestone amount to be received, registrants could group milestones if they believe that this condensed information provides users of their financial statements with more useful information than disclosing each milestone.

Sample comments

(1) You state that you may receive up to $x.x billion and $xxx million of milestones relating to your agreements entered into in 20XX and 20XX. Please provide proposed disclosure to be included in future filings to separately disclose by type (i.e. stage of development) the amount which may be received for individually insignificant milestones and by milestone for individually significant milestones. Please also expand your disclosure in the last paragraph of "Other Collaborations" on page xx to do the same regarding milestones.

(2) We acknowledge your response to our comment x indicating that you have agreements with over xx individual milestones. ASC 605-28-50, nevertheless, requires disclosure of a description of each milestone and related contingent consideration. As previously requested, please provide us proposed disclosure of your milestones. If you believe some form of summarization in the disclosure would comply with this disclosure requirement in all material respects, please provide it to us. In order to evaluate your summarization, separately provide us a listing by contract of each of your discrete milestones showing, for each milestone, the amount and event that triggers its receipt.

(3) Regarding your disclosure related to XX agreement, your basis for determining the milestones to be substantive is not consistent with the three criteria under ASC 605-28-25-2. Please revise your disclosure accordingly or tell us where your existing disclosures discuss the three substantive milestone criteria.

(4) Regarding your third party collaborations discussed here as well as your recent collaboration with [Company] disclosed in your Form 10-Q for the quarter ended June 30, 20XX, please provide us proposed disclosure to be included in future periodic reports of the contingent consideration of each milestone as required by ASC 605-28-50-2.b. and how these milestones are substantive as required by ASC 605-28-50-2.c. and 50-2.d.

Pharmacy benefit management and wholesale distributor revenue recognition

PBM and wholesale distributors have received comments related to revenue recognition from the sale of prescription drugs. The SEC staff has asked registrants to clarify how the delivery requirement for revenue recognition was met in certain circumstances. The SEC staff has required registrants to substantiate how their policy complies with GAAP by referencing the authoritative literature that supports the accounting model. Subscription and loyalty programs are also fairly common in this sector, and the SEC staff has commented on the nature and terms of such programs, including details on return policies, payment terms and cancellation policies, and how these items affect the revenue recognition models.

Sample comments

(1) For your [Segment] you indicate that you recognize revenue from the sale of prescription drugs when the prescription is filled, which is or approximates when the retail customer picks up the prescription. Please substantiate for us how your policy complies with GAAP by referencing the authoritative literature that supports your accounting. In your response, at a minimum, please specifically address the following concerns:

- Please clarify what you mean by the prescription being filled. Explain whether there is anything more involved than a pharmacist or technician extracting bulk drug and packaging the prescribed quantity into an individual vial and applying a customized label to that vial.
- To the extent that you recognize revenue upon the packaging of a prescription for customer pick-up, please address the following:
  - Explain why it is appropriate to recognize revenue before delivery to the customer.
  - Explain when you are entitled to bill the customer's insurance carrier for the prescription. If not until the prescription is actually delivered to the customer, please explain how you reflect the associated receivable on your balance sheet before the amount is actually billed.
  - Explain when you are entitled to bill the customer for his/her co-pay, if any.
  - Explain when you record the associated cost of sale.
  - Tell us the amount of revenue recorded at the end of each of the last three years for prescriptions filled but not yet picked-up by customers.

(2) Please reconsider the appropriateness of the statement included in your response to comment x that you recognize revenue in accordance with Staff Accounting Bulletin Topic 13 and Accounting Standards Codification (ASC) 605 Revenue Recognition. We observe that the delivery requirement for revenue recognition is met when the seller has substantially accomplished what it must do pursuant to the terms of the arrangement, which usually occurs upon delivery or performance of service. Applied to your facts and circumstances, we do not believe that segregating the prescribed product in a separate container and placing it in your "waiting bin" represents delivery in part because the risks of ownership have not passed to your customer at that point. We also are unable to discern from your response that the requirements necessary to recognize revenue when delivery has not occurred (i.e. bill and hold arrangements) have been met. We note that your response cites other "remaining performance obligations" in addition to delivery. It remains unclear to us what those obligations are and whether they too raise question about the appropriateness of the statement cited above.

(3) For your third party pharmacy sales, you indicate that you recognize revenue from the sale of prescription drugs when the prescription is filled, which is or approximates when the retail customer picks up the prescription. Please substantiate for us how your policy complies with GAAP by referencing the authoritative literature that supports your accounting. In your response, at a minimum, please specifically address the following concerns:

- Please clarify what you mean by the prescription being filled. Explain whether there is anything more involved than a pharmacist or technician extracting bulk drug and packaging the prescribed quantity into an individual vial and applying a customized label to that vial.
- To the extent that you recognize revenue upon the packaging of a prescription for customer pick-up, please address the following:
  - Explain why it is appropriate to recognize revenue before delivery to the customer.
  - Explain when you are entitled to bill the customer's insurance carrier for the prescription. If not until the prescription is actually delivered to the customer, please explain how you reflect the associated receivable on your balance sheet before the amount is actually billed.
  - Explain when you are entitled to bill the customer for his/her co-pay, if any.
  - Explain when you record the associated cost of sale.
  - Tell us the amount of revenue recorded at the end of each of the last three years for prescriptions filled but not yet picked-up by customers.
  - Tell us how you consider abandoned prescriptions in your revenue recognition policy.
  - Tell us your policy for determining when a filled prescription is considered abandoned (i.e. after how many days it is determined abandoned). Also tell us the cost of filled prescriptions abandoned for each period presented and where in your consolidated statement of operations you classify abandoned prescriptions.

(4) You discuss on page xx that you continue to promote your product subscriptions and loyalty programs that provide incentives for customer to commit to buying a specified amount on a monthly basis. You further state that xx% of your revenues were derived from subscription orders. Please provide draft disclosure to be included in future filings that address the following:

- The nature and terms of your subscription and loyalty programs, including your return policy, payment terms and cancellation policy;
- The nature of the incentive involved in these programs and whether or not the products are sold at a deeper discount than the wholesale price provided to your distributors;
- The amount of returns you receive under these programs; and
- The method of accounting for the revenue recognized and costs associated with these programs and reference to the authoritative guidance that supports your accounting treatment.

Loss contingencies

The SEC staff continues to focus on ensuring that registrants comply with the guidance in ASC 450, *Contingencies,* related to loss contingency disclosures. The comments provided in this area are generally consistent over the period of our analysis and focus on ensuring that the registrant has made an assessment of the likelihood of loss related to each contingency disclosed. The guidance in ASC 450-20-50 requires disclosure of certain loss contingencies that do not meet the conditions for accrual, including material loss contingencies that are considered probable but not reasonably estimable and those that are at least reasonably possible (but not probable), regardless of whether they are reasonably estimable. For contingencies that meet the criteria for disclosure, registrants should disclose the nature of the contingency and an estimate of the possible loss or range of loss (or a statement that such an estimate cannot be made).

The pharmaceutical and life sciences industry is also focused on FDA warning letters. The SEC staff has asked registrants to enhance disclosures related to FDA warning letters received, and how the disclosures required by ASC 450-20-50 were considered. Considerations on how registrants assessed the necessity of an accrual at the balance sheet date, and on the estimation of probable or possible losses, were consistent with general loss contingency comments throughout the documents.

On July 9, 2012, the Financial Accounting Standards Board (FASB) voted to remove the *Disclosure of Certain Loss Contingencies* project from its agenda. One of the reasons cited by board members for discontinuing the project was improved compliance with existing disclosure requirements as a result of increased SEC staff focus on loss contingencies. One question that might be on the minds of preparers is whether the removal of the *Disclosure of Certain Loss Contingencies* project from the FASB agenda will result in a reduction in the number of SEC staff comments related to contingencies. At the 2012 American Institute of Certified Public Accountants (AICPA) conference on current SEC and Public Company Accounting Oversight Board (PCAOB) Developments, SEC staff indicated that while enhanced disclosures may reduce the overall number of comments in this area, SEC staff comments on contingencies are based on existing accounting guidance, not the proposed guidance that would have been part of the removed project.

Based on these comments at the 2012 AICPA conference, it may be reasonable to assume that the volume of comments may decline but will still remain a subject that will draw attention from the SEC staff. Consequently, pharmaceutical and life sciences registrants should continue to focus on ensuring that the disclosure guidance included in ASC 450 is being appropriately applied.

Sample comments

(1) Refer to your response to prior comment x where you state that you do consider on a quarterly basis whether you can reasonably estimate the range of potential losses of your material loss contingencies and that you would disclose this range as required by ASC 450 if you could reasonably estimate the range of potential losses. Please tell us how you identify your material loss contingencies to consider on a quarterly basis whether you can reasonably estimate the range of potential losses, as opposed to your immaterial loss contingencies. It appears that if you are able to distinguish between material and immaterial loss contingencies, you are able to make an estimate regarding the reasonably possible losses related to your litigation contingencies. Please clarify this matter. Additionally, tell us whether and, if so, to what extent you attempt to quantify the amount of reasonably possible losses for each litigation contingency on a quarterly basis, and if not, please explain your basis for not attempting to quantify those matters. If you maintain that you are not able to estimate a range of reasonably possible losses for each of your litigation contingencies individually or in the aggregate, please tell us the specific reason(s), in addition to the general factors you have already stated in your response, you are not able to estimate such a range.

(2) We see that you have not accrued any amounts in connection with the FDA Consent Decree. Please tell us how you have considered the requirements of FASB ASC 450-20-25-2 in assessing whether an accrual was necessary at the balance sheet date. In that regard, tell us whether you believe a loss is probable and if the amount of loss can be reasonably estimated. Please note that the requirement to estimate the loss should not delay accrual of a loss until only a single amount can be reasonably estimated.

(3) We note from your disclosures on page xx that you received an FDA warning letter related to certain corrective and preventive actions related to your products and quality system related processes. Please tell us how you considered the disclosures required by FASB ASC 450-20-50.

(4) We note the disclosure in your filing related to the [matters] in [states]. Please note that when a loss contingency exists, ASC 450-20-25-1 contemplates an assessment as to whether the loss is probable, reasonably possible or remote. Your disclosure appears to imply that you have determined that a loss contingency exists for each of your current matters but that you have not made such an assessment as to where the loss falls within the range of likelihood. Please make the required assessment for each of your current loss contingencies, describe to us the basis for your conclusion and provide us with your proposed revised disclosures related to each current loss contingency.

(5) Please tell us whether you are not able to estimate the range of loss for several related other civil qui tam actions that are not included in the proposed settlement or why you concluded that the amount is not material. If you are not able to estimate, tell us why the terms of the agreement in principle do not provide sufficient information to make a reasonable estimate of the other civil qui tam actions.

(6) Your note discloses several pending legal proceedings, yet you do not appear to disclose your policy for the accounting for contingencies or the disclosures required by ASC Section 450-20-50. Please provide us proposed policy note disclosure to be included in future periodic reports that indicates your policy for accounting for loss and gain contingencies. In addition, in a risk factor on page xx and in MD&A on page xx, you disclose that litigation and government investigations could result in a material adverse impact on your results of operations, financial condition or cash flows. As a result, it appears at least reasonably possible that a loss may have been incurred. Therefore, please provide us proposed revised disclosure to be included in future periodic reports that discloses:

- The amounts accrued for loss contingencies accrued as required by ASC 450-20-50-1; and
- An estimate of the possible loss or range of loss or a statement that such an estimate cannot be made for loss contingencies that are at least reasonably possible but not accrued, either because it is not probable that a loss has been incurred or the amount of loss cannot be reasonably estimated, as required by ASC 450-20-50-3 and 50-4. If you cannot make an estimate, please disclose the facts and circumstances that prevent you from making such an estimate as well as a discussion of what is being sought in those proceedings.

Taxes

Recent comment letters trends show a continued focus on income taxes. The SEC staff has asked for further explanations relating to the relationships between the changes in a registrant's tax provision and their income or loss before taxes, as well as further discussion of the amount and nature of reconciling items included in the statutory income tax rate to effective tax rate reconciliation in accordance with ASC 740, *Income Taxes*.

The SEC staff also remains interested in registrants' disclosures related to the "practicability" of determining the amount of unrecognized deferred tax liabilities on undistributed earnings. The SEC staff has focused on the specific reasons and disclosures as to why it is "impractical" to determine such amount.

Another recurring income tax theme relates to valuation allowances. The SEC staff has provided comments asking registrants to enhance their disclosures with more detail on the consideration of ASC 740 in determining whether it was more likely than not that its deferred tax assets are realizable and whether a valuation allowance is needed. The SEC staff has asked for a specific discussion of the significant estimates and assumptions used in registrants' analyses, including the specific factors that changed during the periods that led to determination of a valuation allowance reversal or an additional provision.

The SEC staff's comments have requested expanded disclosure to comply with minimum requirements, and as a result of expanding the discussions, some registrants found it necessary to address and explain some items in MD&A as well. The SEC staff's comments often asked registrants to reconcile how the assertions in the tax footnote (e.g., indefinite reinvestment assertion) line up with other disclosures in MD&A around liquidity.

Sample comments

(1) We acknowledge your response to prior comment x. Regulation 4.08 of Regulation S- X requires disclosure of the components of income tax expense where the amount of such tax effect exceeds five percent of the amount computed by multiplying the income before tax by the applicable statutory tax rate. Since it appears that your annual accruals for uncertain tax positions exceed the five percent threshold, please provide us proposed disclosure to be included in future periodic reports showing the amount and nature of this reconciling item of your statutory income tax rate to your effective tax rate as required by ASC 740-10-50-12.

(2) Please clarify for us why you believe it is not "practical" to determine the amount of unrecognized deferred tax liability related to the $xx.x billion in undistributed earnings. Refer to ASC 740-30-50-2.c. which requires disclosure of the amount of unrecognized deferred tax liability, if practicable, or a statement that determination is not practicable.

(3) We acknowledge your response to prior comment x. Since your annual accruals for uncertain tax positions appear to exceed the five percent threshold in Rule 4-08(h) of Regulation S-X, please provide us proposed disclosure to be included in future periodic reports showing the amount and nature of this reconciling item of your statutory income tax rate to your effective tax rate.

(4) Please explain to us why it is appropriate to recognize a benefit in continuing operations of $xx,xxx,xxx in the first quarter of 20XX related to your Phase I clinical services business classified as a discontinued operation in the fourth quarter of 20XX. Tell us whether you rely at least in part on the guidance in ASC 740-10-45-20 and ASC 740-20-45-4, and separately tell us why it was appropriate to record a full valuation allowance at December 31, 20XX for the deferred tax assets recognized in 20XX when you reversed it in the next quarter. Please tell us what factors changed in the first quarter of 20XX causing you to reverse this valuation allowance. Explain why this tax loss would more-likely-than-not be benefitted as a worthless stock deduction in the first quarter of 20XX but not in the fourth quarter of 20XX. Where appropriate, reference for us the authoritative literature you relied upon to support your accounting.

Business combinations and impairment tests

Mergers and acquisitions deal activity has escalated over the years, resulting in an increased consolidation of operations throughout the pharmaceutical and life sciences industry, and also an increased focus on the related accounting. Acquisition-related accounting and disclosure requirements can be complex, depending on the nature of the transaction and the nature of the assets acquired and liabilities assumed. As companies continue to seek growth opportunities through acquisitions, the SEC staff continues to comment on various purchase accounting disclosure items and the subsequent impact of goodwill impairment, as discussed below.

ASC 805, *Business Combinations*, provides extensive disclosure requirements to enable users to evaluate the nature and financial effects of the business combination. Registrants should carefully consider all of the disclosure guidance in preparing financial statements, both in the period of the acquisition and in subsequent periods.

For companies in the pharmaceutical and life sciences industry, the SEC staff comments have focused on valuation matters, recognition of in-process research and development (IPR&D), and other general acquisition accounting matters, including:

- Fair value determination and key assumptions utilized;
- Use of an independent valuation performed by a third-party valuation specialist;
- Recognition of IPR&D activities;
- Allocation of goodwill to reporting units and the interplay with the registrant's operating segments disclosures; and
- The reasons for significant adjustments to the initial purchase price allocation and the reasons why such information was not available at an earlier date.

Sample comments

(1) We note your disclosure herein that fair values for your 20XX acquisition of [Company], Inc. were determined by management based, in part, on an independent valuation performed by a third party valuation specialist. Please describe to us and revise future filings to clarify the nature and extent of the third party valuation specialist's involvement and management's reliance on the work of the independent appraiser. Please refer to Question 141.02 of the Compliance and Disclosure Interpretations on Securities Act Sections, which can be found at http://www.sec.gov/divisions/corpfin/guidance/sasinterp.htm, and which would be applicable to the extent your Form 10-K is incorporated by reference into any registration statement.

(2) On page xx, you indicate that the intangible asset recorded at acquisition of $xxx million relates to [Company]. You also disclose that you acquired the earlier stage development projects in various therapeutic areas of [Company], including the Phase III candidate [product]. Please tell us whether you have recorded indefinite lived intangible assets for the various in-process research and development projects acquired in the [Company] acquisition. If so, please tell us where you have reflected these assets, the amounts recorded and how you determined them. If not, please tell us why not and reference the authoritative literature you relied upon to not record any in-process research and development intangible assets.

(3) We acknowledge your response to our previous comment x. To further assist us in assessing your accounting, please address the following items:

- Please provide us a copy of the valuation report performed at the time of the acquisition to fair value [product] at zero. Our presumption is that this report will provide us the necessary details such as cash flow projections of revenues and costs and the assumptions to understand how a zero fair value was determined. If that is not the case, please include with your response.
- Regarding the contracts with your contract research organizations for the performance of the 1 and 2 Phase III studies, tell us what you mean by a large portion of the costs would be spent whether you chose to end the studies at acquisition or allowed them to continue. In this regard, tell us separately for each study the economic consequence under the contracts of cancelling the study at the time of the acquisition of [Company], comparing that consequence to the amount that would be spent, noting that you did not start the 2 study until the quarter ended September 30, 20XX.
- Please provide us an analysis supporting your assertion on page xx of your June 30, 20XX Form 10-Q regarding the expected launch of [product] by 20XX. Please also tell us the date when your expectation changed to a more realistic launch date in 20XX, your analysis supporting the new date and why you continued to disclose a 20XX launch date in your Forms 10-Q for September 30, 20XX and December 31, 20XX.

(4) On page xx, you disclose your purchase price allocation and that the estimated fair values of assets acquired and liabilities assumed are provisional and subject to change. Please provide us proposed revised disclosure to be included in future periodic reports that:

- Removes reference to a purchase price allocation as that is a construct of the purchase method. Under the acquisition method, assets acquired and liabilities assumed are generally recorded at fair value and goodwill is determined by the excess of the fair value of the consideration conveyed to the seller over the fair value of the net assets acquired.
- Specifically identifies which assets, liabilities or items of consideration are provisional, the reasons why your initial accounting is incomplete and the nature and amount of any measurement period adjustments recognized during the reporting period as required by ASC 805-10-50-6.

Impairment tests

In addition to focusing on business combinations, the SEC staff has continued to issue comments relating to registrants' considerations surrounding the goodwill impairment test. Impairment tests and considerations require judgment and estimates, and registrants are expected to complete a thorough analysis of potential impairments and clearly disclose the assumptions that prompted a determination of whether an impairment exists. Additionally, registrants are expected to provide foreshadowing disclosure related to "close calls."

In accordance with ASC 350, *Intangibles – Goodwill and Other*, registrants are required to perform an annual assessment of the carrying value of their goodwill or interim impairment tests if events or circumstances show that it is more likely than not that the fair value of a reporting unit is below its carrying value.

In September 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-08, *Testing Goodwill for Impairment*; In July 2012, the FASB issued ASU No. 2012-02, *Testing Indefinite-Lived Intangible Assets for Impairment* (collectively, the revised standards). These revised standards provide companies with the option of performing a qualitative assessment to determine whether additional impairment testing is necessary. Registrants should carefully consider whether a qualitative approach is appropriate based on their circumstances, and should ensure that SEC filings include complete and clear disclosures.

As part of the goodwill impairment disclosures, foreshadowing disclosures is another area of SEC staff attention. Registrants should carefully consider disclosing any material information that would assist investors in assessing the potential for future impairments.

Sample comments

(1) With a view toward disclosure in future filings, please tell us whether, based on your most recent testing, you have any reporting units at risk of failure of step one of the goodwill impairment model. To the extent you have one or more reporting units at risk of failing step one of the goodwill impairment testing model, in future filings, please quantify the amount of goodwill associated with those reporting units, describe the methods, models and key assumptions used to test the reporting units for potential impairment, describe the degree of uncertainty associated with key assumptions and clarify the extent to which fair value exceeded carrying value as of the date of the most recent test.

(2) We note that of the total acquisition cost of $xx million, $xxx thousand was allocated to developed technology, $xx.x million was allocated to IPR&D related to the future commercialization of [Company's] [product] device in the U.S. and $xx.x million was allocated to goodwill. In the fourth quarter 20XX, you recorded impairment charges of $xxx thousand of the developed technology and $xx.x million of IPR&D. You did not record any charges for the impairment of goodwill. Please tell us the composition of your reporting units and the amount of goodwill assigned to each reporting unit. For the reporting unit that includes the [Company] goodwill, please tell us the following:

- The percentage by which the fair value exceeded the carrying value as of the date of the most recent test;
- A description of the methods and key assumptions used in the impairment analysis and how the key assumptions were determined;
- Discuss the degree of uncertainty associated with the key assumptions, providing specifics to the extent possible; and
- Describe potential events and/or changes in circumstances that could reasonably be expected to negatively affect the key assumptions.

(3) We note that a result of the change in your [North American] reporting units you recognized a goodwill impairment charge of $xxx million during the first quarter of 20XX. Please revise future filings to expand your MD&A to discuss whether your reorganization and related impairment charges affected your expectations regarding your future operating results and liquidity. Please also discuss the primary underlying factors that resulted in the goodwill impairment charges.

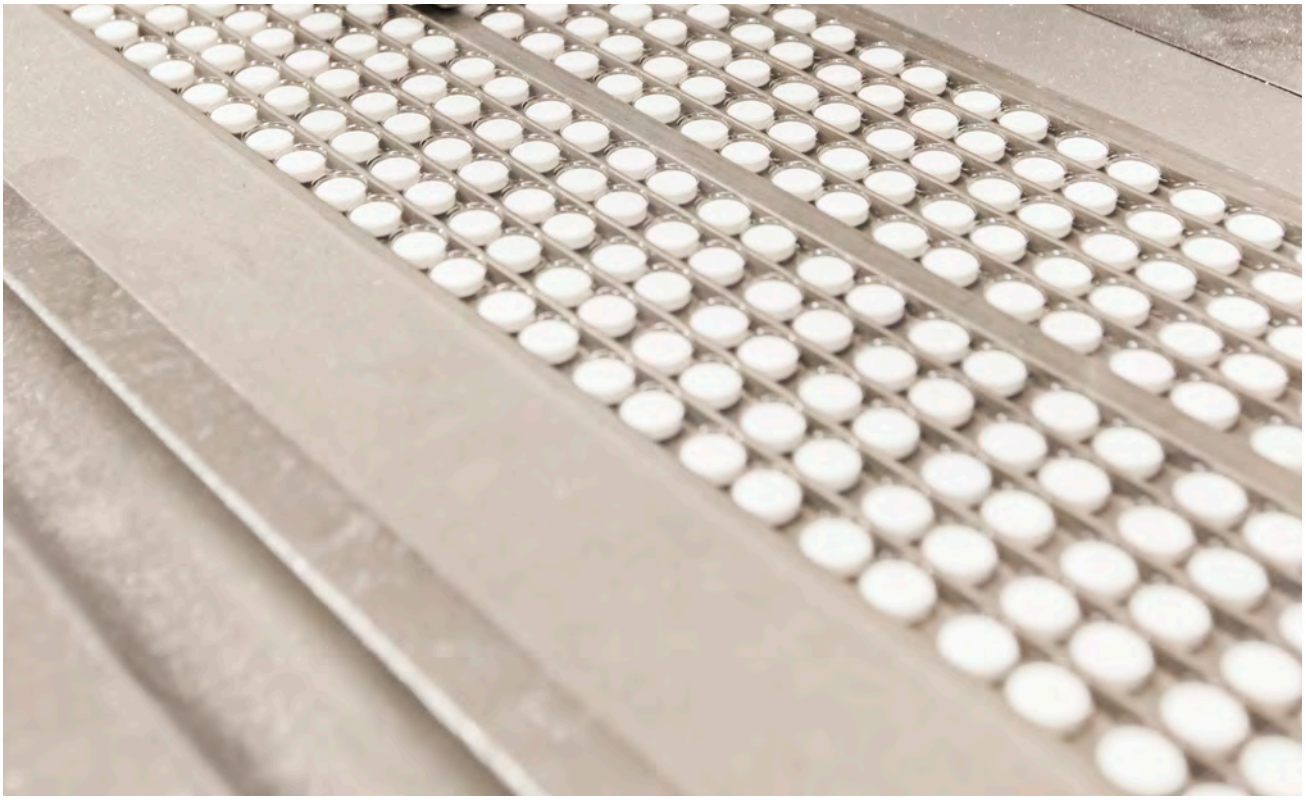
(4) It appears that you treat your reportable segments as reporting units for goodwill impairment testing purposes. Given that you have numerous subsidiaries in various jurisdictions throughout the world as indicated in Exhibit xx and that the profitability of those subsidiaries does not appear to be consistent based on your disclosure of domestic and foreign pre-tax income on page xx, please demonstrate to us why you do not appear to allocate goodwill to components of operating segments under ASC 350-20-35- 34. Please reference for us the authoritative literature you rely upon to support your accounting.

Segment reporting

Segment reporting disclosures have long been a hot topic for comment letters across all industries, and the same holds true for the pharmaceutical and life sciences industry. The SEC staff has provided comments on registrants' segment presentation and whether additional segments should be presented. The comment letters go beyond the financial statement disclosures, and often include comments on the interaction with the goodwill impairment test impacts disclosed in the financial statements and the segment discussion in the MD&A.

The aggregation criteria under ASC 280, *Segment Reporting*, have been a recurring area of the SEC staff's focus when companies with various lines of business or products and operations in multiple geographies disclose single reportable segments. The SEC staff has also provided comments on registrants' conclusions on aggregation of operating segments into reportable segments. It is also not unusual for the SEC staff to request a copy of the chief operating decision maker (CODM) package as further support for the segment conclusions and disclosures provided by registrants. The SEC staff has also asked registrants to demonstrate how the operating segments meet the "economic similarities" criterion for purposes of aggregation.

Entity-wide information about revenues from external customers for each product and service or each group of similar products and services, and information about geographic areas that should be disclosed, has also been at the top of the list of hot topics. The SEC staff's comments have requested that registrants provide an explanation for conflicting disclosures and the rationale when a registrant asserts that disclosure is impractical. The SEC staff may evaluate this assessment compared to how the registrant discusses results of operations in MD&A. To the extent that MD&A provides disclosures explaining variances based on product or service or at a more detailed level, the SEC staff may question the registrant's assertion of impracticability. Changes in management and corporate structure may also lead the SEC staff to provide a comment asking for more information on how such changes impact the CODM reporting package.



Sample comments

(1) Please revise your proposed disclosure provided in response to comment x to disclose your revenue by the product/service groups identified on pages xx through xx of your filing. If you believe it is appropriate to group products/services at your reportable segment level, please explain to us why. In this regard, for example, it does not appear that the cardiology, women's health, infectious disease, oncology and toxicology offerings of your [Segment] are similar. On the other hand, if you believe providing this information is impracticable, please explain to us why and revise your proposed disclosure to disclose this fact.

(2) You disclose that you operate in a single segment and that the segment information you present is consistent with the financial information regularly reviewed by the chief operating decision maker, your chief executive officer, for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting future periods. Please demonstrate to us how you have one operating segment and reference the authoritative literature you rely upon to support your position.

In your response, please explain why the six geographic regions identified in the table at the bottom of page xx are not operating segments. From your list of executive officers on page xx, it appears that you may have presidents for each of your reported geographic regions. Please explain why these presidents are not the segment managers identified in ASC 280-10-50-7. In addition, please provide us with one set of the reports your chief executive officer regularly reviews to evaluate performance, allocate resources, etc. and tell us the frequency with which he reviews these reports. Tell us whether he reviews any other reports on a less frequent basis and, if so, describe those reports.

(3) We note your response to prior comment x. You state that although your chief operating decision maker receives information regarding sales, gross margin and operating profitability by geographic location, he does not use such information to make resource allocation decisions. Please address the following:

- Provide us with a more complete analysis of how you considered FASB ASC 280-10- 50-1(b). In this regard, your response does not address whether this information is used in assessing performance.
- In light of your assertion that your chief operating decision maker does not utilize this information in making resource allocation decisions, explain to us in greater detail the specific reasons why such information is included in the package provided to your chief operating decision maker.
- Since information regarding results by geographic location is included in the package provided to your chief operating decision maker, it would appear that such information would inherently be considered in the decisions regarding resource allocation, whether directly or indirectly. Explain in greater detail why you believe that resource allocation decisions are made exclusive of this information that has been provided to your chief operating decision maker. Discuss how you are able to ensure that such information is not considered in making resource allocation decisions.
- In order to provide greater insight into your resource allocation decisions, please provide us with additional information regarding how you developed your plans in regards to the September 20XX restructuring, including the information your chief operating decision maker used to evaluate the restructuring plan prior to approval.
- In order to assist us in our evaluation of your segment disclosures, please provide us with a sample of the reporting package provided to your chief operating decision maker.

(4) We note your response to prior comment x. We further note the reference to your Board of Director's recent appointment of a new CEO in September 20XX. You state that the new CEO has announced his intention to report your results separately based on two divisions focused on the two primary market segments in which you compete. Please address the following:

- If available, provide us with an estimate of the timing of the change in your reporting structure.
- In light of the stated intention to change the reporting structure, tell us how, if at all, the reporting package currently being provided to your chief operating decision maker differs from that addressed in your response to our prior comment.

Other notable trends

10-K and 10-Q Compliance

During the year-end and quarterly financial reporting process, management should devote a significant amount of effort to ensuring that transactions are appropriately reflected in the registrant's financial statements and SEC disclosures, so that the information included in the filing is accurate and meets the needs of investors. In addition, compliance with the instructions to Form 10-K and Form 10-Q, particularly as related to signatures and exhibits, is critical. Regulation S-T outlines the general rules and regulations for electronic filings, while Regulation S-K outlines requirements specific to filings under the Securities Act of 1933, Exchange Act of 1934 and Energy Policy and Conservation Act of 1975.

As registrants prepare their year-end financial statements, management should revisit this guidance to ensure compliance with the requirements. Comments in this area primarily relate to the dates and language included in certifications of the financial statements by the chief executive and chief financial officer, as required by the Sarbanes-Oxley Act outlined in Regulation S-K, Item 601(b)(31), and with the exhibits and appendices that are required to be included and referenced within the filing, primarily focused on exhibits for material contracts as required by Regulation S-K, Item 601(b)(10). For example, the SEC staff may request amendments to any filings that do not include required signatures in typed forms or all of the appropriate exhibits and material contracts.

Sample comments

(1) Please file as exhibits or incorporate by reference to those material contracts, as required by Form 10-K.

(2) When you amend your filing, please revise your certifications to present the exact form and wording of the certifications required by Item 601(b)(31) of Regulation S-K. For example, the certifications required by Item 601(b)(31) do not refer to a "small business issuer." Similar concerns apply to the amendment you will need to file for your Form 10-K for fiscal year ended 20XX.

(3) Please file all material agreements required by Item 601(b)(10) of Regulation S-K. For example, and without limitation, we note your reference at page xx to agreements related to your XX.

Operations of locations identified as state sponsors of terrorism

The SEC staff regularly asks registrants, particularly global organizations, to provide incremental information about business activities in or with countries identified by the US State Department as state sponsors of terrorism (currently, Cuba, Iran, Sudan and Syria). Additionally, the SEC staff periodically requests updates on those activities if a registrant has been identified as having any business operations in or with one of those countries. Rule 408 of Regulation C and Exchange Act Rule 12b-20 require disclosure of additional information if it constitutes material information that is necessary to make a registrant's disclosure in its filings not misleading, given the registrant's facts and circumstances. As a result, the SEC staff has frequently requested registrants to provide, and, based on materiality, to disclose, the following information regarding state sponsors of terrorism:

- Nature and extent of past, current, and any anticipated operations in or with a country designated as a state sponsor of terrorism, whether through subsidiaries, affiliates, joint ventures, alliances, distributors, resellers, or other arrangements,
- Any agreements, goods, services, technology, or support that registrants have provided for the referenced countries or any agreements or other contracts that the registrant has had with the governments or entities controlled by the governments in these countries,
- Whether there are offices, facilities, equipment, ground services, sales agents, or other employees in such countries, and
- Whether operations in or with state sponsors of terrorism constitute a material risk.

With respect to determining whether operations in or with state sponsors of terrorism constitute a material risk, the SEC staff frequently comments that materiality should be addressed based on both quantitative and qualitative factors. For quantitative factors, the SEC staff will ask for the approximate dollar amount of any revenues, assets, and liabilities associated with such sponsors for the last several (often three) years and subsequent interim periods. The SEC staff will also ask for a qualitative assessment of factors that a reasonable investor would deem important in making an investment decision, including the potential impact of corporate activities upon a registrant's reputation and share value.

Further, on Aug. 10, 2012, President Obama signed into law the Iran Threat Reduction and Syria Human Rights Act of 2012, which requires a registrant that files Exchange Act periodic reports to provide disclosure in its periodic report if during the reporting period it or any of its affiliates has knowingly engaged in certain specified activities involving contacts with or support for Iran or other identified persons involved in terrorism or the creation of weapons of mass destruction.

Sample comments

(1) We note that [Company A's] website has a job posting for a company called [Company B], and the posting states that this company holds the representation of some products of pharmaceutical companies including [Company C]. We also note that in 20XX your website listed Iran and Syria as countries covered by your Middle East region. Iran and Syria are identified by the State Department as state sponsors of terrorism and are subject to U.S. economic sanctions and export controls. We note that your Form 10-K does not include disclosure about Iran or Syria. Please describe to us the nature and extent of your past, current, and anticipated contacts with Iran and Syria, whether through subsidiaries, distributors, resellers or other direct or indirect arrangements. Your response should describe any services or products you have provided to Iran or Syria, and any agreements, commercial arrangements, or other contacts you have had with the governments of those countries or entities controlled by those governments.

(2) Please discuss the materiality of your contacts with Iran and Syria described in response to the foregoing comment and whether those contacts constitute a material investment risk for your security holders. You should address materiality in quantitative terms, including the approximate dollar amounts of any associated revenues, assets, and liabilities for the last three fiscal years and the subsequent interim period. Also, address materiality in terms of qualitative factors that a reasonable investor would deem important in making an investment decision, including the potential impact of corporate activities upon a company's reputation and share value. Various state and municipal governments, universities, and other investors have proposed or adopted divestment or similar initiatives regarding investment in companies that do business with US-designated state sponsors of terrorism. Your materiality analysis should address the potential impact of the investor sentiment evidenced by such actions directed toward companies that have operations associated with Iran and Syria.

Non-GAAP measures

Non-GAAP measures have long been a recurring topic in the SEC staff comment letter process across all industries. The SEC staff has provided comments on registrants' presentation of non-GAAP measures and compliance with the disclosures required by Item 10(e) of Regulation S-K. A non-GAAP financial measure is a numerical measure of historical or future financial performance, financial position or cash flows that excludes items that are included in the most directly comparable GAAP measure or that includes items that are excluded from the most directly comparable GAAP measure. When non-GAAP financial information is presented in periodic reports filed with the SEC, registrants are required to include in their disclosures:

- A statement of the reasons why management believes that the non-GAAP measure is relevant to investors;
- A statement disclosing the additional purposes, if any, for which management uses the non-GAAP financial measure;
- A presentation with equal or greater prominence of the most directly comparable financial measure presented in GAAP to facilitate comparability among other registrants; and
- A reconciliation to the comparable GAAP measure.

At the 2012 AICPA conference, the SEC staff cautioned that it had seen certain non-GAAP measures that are misleading and therefore not permitted, and reminded attendees about the importance of complete disclosure.

Recent comment letter trends highlight the SEC staff's efforts to ensure that registrants are focused on compliance with non-GAAP disclosure guidance. Caution should be exercised when evaluating whether to disclose non-GAAP measures, which measures to disclose, and how to present those measures.

Sample comments

(1) We note your income statement presentations excluding the effect of the 1 Rebate Program and class action settlement. While disclosure and discussion of the effect of the 1 Rebate Program and class action settlement is meaningful, your current presentation results in the presentation of numerous non-GAAP financial measures for which you have not included the disclosures required by Item 10(e) of Regulation S-K. In addition, in Non-GAAP Financial Measures Compliance and Disclosure Interpretation 102.10, which is available on our website at http://sec.gov/divisions/corpfin/guidance/nongaapinterp.htm, the Staff has indicated that such a presentation may attach undue prominence to the non-GAAP information. Please revise future filings to remove the non-GAAP income statement and instead provide a clear, separate presentation and discussion of each non-GAAP financial measure presented. Please note this comment also applies to the presentation in your Item 2.02 Form 8-K earnings releases. Please provide us a sample of your proposed revised disclosures.

(2) We note your response to prior comment x. We are unable to agree that your current presentation is appropriate and consistent with the guidance in Item 10(e) of Regulation S-K as further discussed in the Staff's Non-GAAP Financial Measures Compliance and Disclosure Interpretation 102.10. We believe your current presentation whereby you present a non-GAAP income statement and provide a discussion of the results of operations using only the non-GAAP income statement information attaches undue prominence to the non-GAAP financial measure. We note similar presentation in your Forms 10-Q for the quarters ended June 30 and September 30, 20XX. Please amend each of your June 30, September 30 and December 31, 20XX to remove the non-GAAP income statement presentation and instead separately disclose only those non-GAAP measures used by management that you wish to highlight for investors. Please note this comment also applies to your future Forms 8-K.

(3) Notwithstanding the above, we note your proposed revised disclosures regarding the use of the non-GAAP financial measures. However, we note the proposed disclosure does not provide the disclosures required by Item 10(e) of Regulation S-K for each non-GAAP measure presented. Please further revise the disclosures.

(4) We see that you disclose Adjusted EBITDA as a percentage of Net Sales in the table on page xx and include a definition of this non-GAAP measure on page xx. Please revise future filings to provide all the disclosures required by Item 10(e) of Regulation S-K, including a reconciliation of the non-GAAP measure to the most directly comparable GAAP measure, the reasons why management believes the measure provides useful information to investors and the additional purposes for which your management uses the non-GAAP measure.

Another recent topic

Emerging markets - China

Although not yet a current trend as identified in our analysis, recent SEC staff comments have focused in part on risks associated with emerging markets such as China. The legal environment in China can result in specific risks or circumstances that require additional disclosures. As US business in China continues to grow, the SEC is likely to increase its focus in these areas.

Sample comments

(1) Please revise your disclosure under this risk factor heading to discuss in greater detail the landscape of intellectual property protection in China. For example disclose that historically, the legal system and courts of the PRC have not protected intellectual property rights to the same extent as the legal system and courts of the United States. Companies operating in the PRC continue to face an increased risk of intellectual property infringement. Furthermore, you should disclose that the validity, application, enforceability and scope of protection of intellectual property rights for many internet-related activities, such as internet commercial methods patents, are uncertain and still evolving in China and abroad, which may make it more difficult for you to protect your intellectual property, and could have a material adverse effect on your business, financial condition and results of operations.

(2) We note you disclose that you operate in a single operating segment and you state that you do not use profitability reports on a regional or divisional basis for making business decisions. Although you do not use these reports, you make reference on page xx in Management's Discussion and Analysis that your margins vary from product to product and "are higher in some markets such as Japan." Please explain why margins are higher in Japan and whether knowledge of this information influences or results in allocations of resources. We further note your business model in China results in a different distribution model of retail stores and that China requires that the company manufacture the bulk of the products distributed in China. You disclose on page xx that "gross profit may fluctuate as a result of changes in the ratio of self-manufactured products and products sourced from third party suppliers." Please tell us how you considered the above items when identifying your operating and reporting segments in accordance with ASC 280-10-50. Please also provide us with a courtesy copy of the financial package used by the chief operating decision maker to assess performance and allocate resources to support the assertions in your response.

Additional consideration for IFRS filers

In addition to the trends analyzed for US GAAP filers, this section sets out considerations for IFRS filers. Recent trends for SEC staff comment letters in the pharmaceutical and life sciences industry for Foreign Private Issuers (FPIs) reporting in accordance with IFRS as issued by the IASB have consisted of (1) inclusion and presentation of non-GAAP measures, (2) expanded disclosures of provisions and contingencies, (3) impairment, (4) expanded disclosures in the MD&A particularly related to research and development activity, (5) and risk factors expected in the pharmaceutical and life sciences industry.

Financial statement presentation and non-GAAP measures

General Instructions C(e) of Form 20-F refer to Item 10(e) of Regulation S-K 10 (S-K 10) to explain the SEC's policy on the use of non-GAAP financial measures. S-K 10 provides that non-GAAP financial measures exclude measures required to be disclosed by GAAP, Commission rules, or a system of regulation of a government or governmental authority or self-regulatory organization that is applicable to the registrant. However, the financial measure is required to be presented outside of the financial statements unless the financial measure is required or expressly permitted by the standard setter that is responsible for establishing the GAAP used in such financial statements.

For FPIs, careful consideration should be given to the disclosure of non-GAAP measures and the presentation of those measures. The SEC staff consistently issues comments requesting:

- How their disclosures complied with Item 10(e) of Regulation S-K and with the Compliance and Disclosure Interpretations (CD&I);
- Modifications due to prominence placed on non-GAAP measures;
- The removal of non-GAAP measures from the notes to financial statements; and
- A quantitative reconciliation of the differences between the non-GAAP financial measure disclosed with the most directly comparable measure or measures presented in accordance with GAAP.

In certain cases, IFRS permits or requires the inclusion of non-GAAP measures. For example, under IFRS 8, *Operating Segments* (IFRS 8) a filer is required to disclose in their segment footnote, the performance measure used by the CODM to allocate resources between segments.

Sample comments

(1) Please amend your filing to remove your financial resources and free cash flow information from the face of your financial statements. Please see Item 10(e)(1)(ii)(C) of Regulation S-K which precludes the disclosure of non-IFRS measures on the face of your financial statements or in the accompanying notes. If you amend your financial statements in a Form 6-K, please amend your 20XX Form 20-F to include reference to the Form 6-K containing your amended Annual Report.

(2) Item 10(e)(1)(i)(A) of Regulation S-K requires that IFRS measures be presented with equal or greater prominence than non-GAAP measures. Although you provide your IFRS information prior to your core financial measures in the tables on page xx, you discuss your core operating results before your IFRS operating results in this section and appear to discuss only your core financial measures elsewhere in your filing. As examples, it appears that you discuss only core financial measures in the following disclosures:

- On the inside cover of your Annual Report you disclose core operating profit and core EPS but not the IFRS equivalents;
- On page xx you disclose core R&D expenditures but not the IFRS equivalents;
- Your strategy and performance disclosures beginning on page xx appear to disclose only core financial measures; and
- Your delivering your strategy disclosures beginning on page xx appear to disclose only core financial measures.

(3) You disclose 'debt, net of cash and cash equivalents' and 'gearing ratio' and indicate that these are non-GAAP measures. As the disclosure of non-GAAP amounts in the notes to the financial statements is precluded under Item 10(e)(1)(ii)(C) of Regulation S-K, please represent to us that you will remove these disclosures in future Forms 20-F. Otherwise, please explain to us why these disclosures in the financial statements are appropriate and reference for us the authoritative literature relied upon to support your position.

Provisions and contingencies

The SEC staff continues to focus on the required disclosures related to the amounts of provisions recognized and for the contingent liabilities disclosed as required under IAS 37, *Provisions, Contingent Liabilities* and *Contingent Assets* (IAS 37).

This area is a particular focus for the pharmaceutical and medical device sectors, which face significant litigation. Trends relate to requests for (1) further details of the methods and assumptions used in provision calculations, (2) supporting analyses for management's consideration of IAS 37 requirements, (3) expanded disclosure of the nature of provisions established, and (4) further disclosure of the financial effect for each contingent liability. If it is determined that the required disclosures are not practical for a certain class of contingencies, that fact must be stated. In some instances, the SEC staff has challenged the aggregation of specific provisions into classes.

Sample comments

(1) You indicate that the [Company] is involved in certain legal proceedings, where it is not possible to make a reliable estimate of the expected future financial effect. For legal proceedings where the possibility of an outflow in settlement is other than remote, please provide us proposed disclosure to be included in future periodic filings showing, for each class of contingent liability, the disclosures described in paragraphs 86-92 of IAS 37, such as a description of the nature of the contingent liability and an estimate of the related reasonably likely financial effect.

(2) You do not appear to have provided all of the disclosure described in paragraphs 84-85 of IAS 37. Please provide us proposed disclosure to be included in future filings or explain to us your basis for omitting this information.

Impairment

With a challenging current economic environment, the SEC staff has been focused on the impairment analysis of the registrants' receivables.

The uncertainty in the Eurozone has increased the importance of transparent disclosure for the pharmaceutical and life sciences industry. Consistent with comments received by US GAAP filers, comment letters have focused on the level of disaggregation in, and the disclosure with respect to the registrant's exposures in those affected territories.

Sample comment

(1) Please provide us a breakdown of gross overdue receivables as of December 31, 20XX and June 30, 20XX or more recent date, if available, by country. For each country show a breakdown by amounts due from or dependent on the government and those that are not.

Tell us which of these receivables and how much are included in the xxx million impairment reserve at December 31, 20XX. Tell us the amount of overdue receivables that have been impaired subsequent to December 31, 20XX. Provide us your analysis as to why you believe gross overdue receivables that are not impaired are collectible.

MD&A—Research and development activity

Item 5 of Form 20-F requires a discussion of the results of operations, trends and uncertainties consistent with the MD&A expectations of domestic registrants. The SEC staff continues to request expanded discussion of financial performance to provide relevant and transparent financial information to investors. Frequently, the SEC staff will compare information discussed in MD&A with the financial statements to identify inconsistencies.

Recently, comment letters have been issued to FPIs in the pharmaceutical and life sciences industry requesting expanded disclosure of R&D activity, patents and licenses. Recurring comments requested the following:

- Further information about key projects including (1) dates they transitioned to various phases, (2) significant patents and expiration dates, (3) patent protection and loss of exclusivity, including the estimated impact on net income related to those elements, (4) required regulatory approvals, and (5) expanded discussion of R&D expense forecasts with reference to the expected completion of projects;
- Identification of additions and removals of key projects from the previous period with a discussion of management's decision to terminate projects that did not commercialize;
- Disaggregation of R&D expenses at the level management examines its R&D function.

Sample comment

(1) In order to help us evaluate your disclosure about your research and development activities, please provide us the following information:

- A description of your research and development process for each of your segments, including to what extent regulatory approval is required to market products. In your response, please describe the key management activities within your "development paradigm," particularly the "confirmatory" phase, including a description of your process for monitoring development progress for individual project projects (e.g. board reviews), your criteria for prioritizing and funding projects, your key decision points for determining project continuance or termination and financial measures used to evaluate performance of your "development paradigm."
- For each segment that requires regulatory approval, quantify the number of projects that were in preclinical development and Phase I, Phase II and Phase III of clinical development and those for which a submission requesting regulatory approval was filed as of December 31, 20XX.
- For each segment requiring regulatory approval, the breakout of research and development expenses incurred during 20XX, if practicable by development phase (i.e., preclinical, Phases I, II and III) and by therapeutic class.
- For your key projects in the Confirmatory development stage listed in the Selected Development Projects table, indicate the month and the year that it entered that phase.
- For your key projects in the Confirmatory development stage listed in the Selected Development Projects table, identify the significant patents associated with the project and their expiration date.
- For your key projects in the Confirmatory development stage listed in the Selected Development Projects table, tell us the projects added to and deleted from the table since 20XX. For those removed from this table clarify whether they were commercialized or terminated. For each terminated project, such as those listed on page xx, disclose the events and their timing leading to your decision to terminate the project.
- Tell us about any Confirmatory development stage projects that are not listed here and the reason not listed.

Risk factors

Item 3.D of Form 20-F requires prominent disclosure of risk factors that are specific to the company and its industry in a section headed "Risk Factors." The SEC staff's comments have consistently focused on the specificity of risk factors and clarity of how the risk affects the registrant. In addition, when a company has experienced any problems with the identified risk factors, the SEC staff has requested a revision to describe the problems.

As it relates to FPIs in the pharmaceutical and life sciences industry, the SEC staff has requested the addition of the following specific risk factors:

- Pending expiration of material patents, trademarks, or patents;
- Factors related to countries in which the company operates, including foreign laws that may impose obligations and liabilities on a shareholder that U.S. states do not impose upon shareholders; and
- For registrants with auditors that are not subject to PCAOB review, a risk factor that states that the PCAOB is prevented from regularly evaluating the auditor's audits and its quality control procedures.

Sample comment

(1) Please add a risk factor that discloses that the deposit agreement governs the rights of ADR holders to receive dividends or other distributions, and discusses whether under the deposit agreement, ADR holders may not have the same rights to, and in some circumstances, may not receive dividends or other distributions issued by you to ordinary shareholders.

About PwC's Pharmaceutical & Life Sciences Industry Group

PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. As a leader serving the industry with more than 3,000 industry-dedicated partners and staff worldwide, we provide audit and assurance, tax and advisory services to an array of both top tier and middle market companies. We have specialized advisory capabilities in research and development, supply chain management, and sales and marketing, as well as in key operational areas, including finance, regulatory compliance, corporate development, information systems and human resources management. Our commitment to the industry is broad-based and our clients include proprietary and generic drug manufacturers, wholesalers and distributors, specialty drug companies, medical device and diagnostics suppliers, biotechnology companies, pharmacy benefit managers, contract research organizations, and industry associations.

A leading global network of professional services firms, with 180,000 people located in 158 countries, PwC delivers quality and excellence across our solutions. The partners and staff in our member firms are dedicated to developing fresh perspectives and practical advice with the aim of creating lasting value for our clients.

For more information about this publication or PwC, please contact:

Karen Young
US Pharmaceutical &
Life Sciences Assurance Leader
karen.c.young@us.pwc.com
(973) 236-5648

Visit our website at: **www.pwc.com/pharma**

Acknowlegements

This publication represents the efforts and ideas of many individuals within PwC, including members of the US Pharmaceutical & Life Sciences Industry Group and the National Professional Services Group. The following PwC personnel contributed to the content or served as technical reviewers of this publication:

Kevin Burney, Partner

Brett Cohen, Partner

Owen Davis, Partner

John Hayes, Partner

Guilaine Saroul, Director

Francesca Bellome, Senior Manager

Fabiana Turri de Genaro, Senior Manager

www.pwc.com

NY-14-0116