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Life Sciences Spotlight

Accounting Implications of Regulatory and Self-Reported Safety Concerns

In This Issue:

The Bottom Line

- Significant regulatory-related actions can have not only business, but also accounting and disclosure, implications — potentially even resulting in the write-down of various assets on a life science company's balance sheet.
- Certain events, such as FDA warning letters requiring corrective actions, voluntary or involuntary product recalls, and clinical study holds and terminations, may trigger a requirement to perform an impairment assessment of properties and intangibles.
- In addition, when the impairment assessment is performed, the assumptions used to measure fair value will often need to incorporate the expected effects of the regulatory action; estimating these factors may require significant judgment.
- Life science companies should remain alert to the financial reporting implications of regulatory-related events so that impairment considerations are promptly identified and carefully evaluated.

Regulatory actions can have immediate accounting ramifications, such as triggering impairment analysis on various classes of assets.

Beyond the Bottom Line

This *Spotlight* highlights the asset impairment considerations associated with regulatory-related events occurring in the life sciences industry.

Background

In light of market and regulatory changes in recent years, such as the Patient Protection and Affordable Care Act of 2010 (the "PPA Care Act"), regulatory bodies like the Food and Drug Administration (FDA) have refocused their strategic priorities to more stringently monitor and enforce safety guidelines that protect public health. The FDA's recently released, final version of *Strategic Priorities 2011–2015: Responding to the Public Health Challenges of the 21st Century* notes:

> A key priority for [the] FDA is improving the safety and effectiveness of medical products, both through rigorous review of clinical studies and manufacturing process information before products are approved as well as through monitoring actual patient experiences and manufacturing quality once they are on the market.

In addition, in line with the FDA's increased focus on safety and monitoring, there has been a shift in public expectations for life science companies to voluntarily recall products or place clinical studies on hold in the event of potential safety concerns. Further, the PPA Care Act has given the FDA the authority and responsibility to regulate biosimilar biological products, a newly defined class of medical products, which further expands the FDA's regulatory footprint. These factors all contribute to a regulatory environment in which there is an increased likelihood of regulatory-related events that could have accounting and financial reporting implications.

Current regulatory environment conditions increase the possibility that regulatory-related actions could have accounting and disclosure implications.

Potential Asset Impairment Triggers

Regulatory actions not only can be detrimental to a life science company's long-term growth prospects but can have immediate financial reporting implications, such as a requirement to perform an impairment analysis on various classes of assets. In response to an adverse regulatory event, life science companies should consider the following:

- *Long-lived assets, finite-lived intangibles, and indefinite-lived intangibles other than goodwill* — These assets are to be tested for impairment whenever events or changes in circumstances indicate that a carrying amount may not be recoverable. Such instances could result from (1) a significant adverse change in the extent or manner in which an asset (or asset group) is being used or (2) a significant adverse change in legal factors or in the business climate that could affect the value of an asset (or asset group), including an adverse action or assessment by a regulator.
- *Goodwill* — The goodwill of a reporting unit should be tested for impairment between annual tests if the occurrence of an event or a change in circumstances would more likely than not reduce the fair value of a reporting unit below its carrying amount. Such instances could result from an adverse action or assessment by a regulator.

The mechanics of a triggered impairment assessment differ by asset type. For example, an impairment assessment of a long-lived asset or a finite-lived intangible is a two-step test in which a company must test for recoverability by comparing the carrying amount with the sum of the undiscounted future cash flows and then measure impairment loss by comparing carrying value with fair value. In contrast, the impairment assessment of an indefinite-lived intangible is simply a comparison of carrying value to fair value. Nevertheless, a company uses many inputs and assumptions in estimating both undiscounted future cash flows and fair value and these inputs and assumptions are often affected by a significant regulatory event.

The discussion in the following sections provides insight into specific events that could

potentially trigger an impairment analysis and related considerations for developing expected future cash flow estimates and fair value measurements. While the examples primarily focus on regulatory considerations in the United States, similar scrutiny and monitoring is occurring globally. Thus, events or circumstances could arise in foreign markets and may require similar consideration.

Companies may also need to consider the disclosure impact of triggering events, particularly since the SEC staff has continued to provide comments to registrants with significant internal R&D expenses, significant acquired in-process R&D assets, or both. These comments have focused on disclosures about internal R&D expenses and estimated future expenses, as well as the types of activities and elements included in R&D expenses and the amount of R&D expenses incurred during each reporting period. Further, registrants may be asked to revise their MD&A and business section to disclose information about each major R&D project (if current disclosures are inadequate). Such disclosure would include consideration of significant triggering events that may be affecting a major R&D project.

FDA Warning Letters on Manufacturing Facility Compliance

The FDA has issued a number of warning letters related to manufacturing quality, safety, and other issues at manufacturing sites. These warning letters may affect a company's ability to continue to produce and ship products from these locations or may delay approval of new drugs until the identified issues are resolved to the FDA's satisfaction. As a result, the receipt of an FDA warning letter may be considered a triggering event requiring an impairment assessment of a manufacturing asset (or group of assets).

Regulatory actions may result in the need to measure an affected asset's fair value.

In determining the expected future cash flows of a manufacturing asset (or group of assets), a company would consider entity-specific assumptions, including the estimated costs of addressing the violations identified in the warning letter if resolution is intended. Separately, in determining the fair value of a manufacturing asset (or group of assets), a company would need to consider the assumptions of market participants, such as the highest and best use. However, a company would need to incorporate the costs of converting or transforming an asset (or group of assets) into measuring whether an alternative use maximizes the value of an asset to a market participant.

In addition to the long-lived asset considerations discussed above, inventory valuations (including capitalized prelaunch inventory) should be revisited to ensure that lower-of-cost-or-market assumptions remain appropriate. Furthermore, management may need to consider the MD&A disclosure impact of the FDA warning letter.

Product Recalls

Product recalls, whether voluntary or involuntary, may affect the long-term revenue prospects for a product, particularly when alternative products are available. A significant decline in future expected product sales not only may trigger an impairment analysis of related intangible assets but could significantly affect their calculated fair value.

In assessing the fair value of an intangible asset, a company would consider a number of factors in estimating the forecasted future cash flows, such as the following:

- Any expected decrease in forecasted revenues because of lost product confidence.
- The remaining product exclusivity period and time frame needed to regain market share, which may not reach the same levels expected before the recall.
- Any shift in the timing of cash flow activity because of the resolution of the product recall issues.
- Marketing spending and other costs necessary to regenerate the market

positioning and share lost while the product was off the market.

- Third-party analysts' expectations for future product sales and market growth, as well as the past performance of similar products in the market.

In addition to the intangible asset considerations discussed above, inventory valuation and sales return assumptions may need to be revisited to ensure that reserves reflect these new circumstances. Furthermore, management may need to consider the MD&A disclosure impact of the recall.

Clinical Study Holds or Termination

Clinical studies are closely monitored and reviewed by the FDA for compliance violations or safety concerns of the participants. Through this monitoring, clinical studies may be put on hold or terminated, either at the direction of the FDA or voluntarily by life science companies. These actions may necessitate an impairment assessment (or entire write-off in the event of termination) of previously acquired in-process R&D assets.

In assessing the fair value of an in-process R&D asset, a company would consider a number of factors in estimating the forecasted future cash flows, such as the following:

- The revised forecasted future cash flows expected once a product receives regulatory approval, which includes any shift in the timing of such cash flow activity because of the clinical study on hold or the start-up of new studies.
- Shifts in expected milestone receipts, if any, on the basis of the delayed approval of a commercial product or the achievement of other milestones.
- Third-party analysts' expectations for future approval and product sales, as well as the past performance of similar products, once approved, in the market.
- The impact that any delay to market could have on forecasted revenues if a competitive product were to reach market earlier.

A company may need to consider a number of factors specific to the regulatory development in estimating future cash flows.

If the study or product in development is significant to the company's R&D efforts, management may further consider whether these events and the company's planned actions should be disclosed in MD&A.

Thinking Ahead

Life science companies should carefully consider the impact that significant regulatory-related events have on asset valuations. While the considerations discussed above may be relevant to many life science companies, they do not represent an all-inclusive listing of the triggers and factors to be considered; the extent of the accounting and disclosure impact will depend on specific facts and circumstances. However, given the potential significance, life science companies can benefit by ensuring such assessment is not an afterthought in the financial reporting process.

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