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Life Sciences
Accounting and Financial Reporting Update

March 2014

Life Sciences Industry

Contents

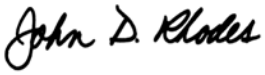
Foreword

March 2014

We're pleased to present our fifth annual Accounting and Financial Reporting Update for the life sciences industry. This publication provides perspectives on a selection of key industry trends, SEC-related matters, accounting hot topics, and standard-setting developments.

The industry is exhibiting resilience and reinvention as it employs new strategies — affecting research and development and business models — to cost-effectively deliver innovation, value, and improved patient outcomes. As always, finance and accounting professionals must ensure that the accounting and reporting implications of implementing these strategies are considered.

We hope you find this update a useful resource, and we welcome your feedback. In addition, we encourage you to contact your Deloitte team for additional information and assistance.



John D. Rhodes
Global Life Sciences Sector Leader, Deloitte Touche Tohmatsu Limited, &
Industry Professional Practice Director, Deloitte & Touche LLP

Industry Outlook

Global Perspectives[1]

The life sciences sector — which comprises the pharmaceutical, biotechnology, and medical technology segments — remained less affected by the recent global economic uncertainty in certain parts of the world; however, it is facing reimbursement pressure from escalating costs and overwhelmed health systems across the world. Still, an overview of recent sector performance shows that it is favorably positioned to achieve success in 2014 and beyond. Among drivers for growth are an aging population, rising incidence of chronic diseases, technological advancements and product innovation, and certain anticipated impacts from health care reform provisions, including increases in government funding and insurance coverage. Opportunities in emerging markets could continue to be a driver, although many companies are looking more cautiously at these markets because of slowing growth and other pressures.

The fundamentals driving health care demand, combined with the advent of new and often more expensive treatments, are expected to boost global **pharmaceutical** sales by an annual average of 5.3 percent through 2017. Sales growth will continue to come from the United States, the United Kingdom, and the BRIC countries. Among BRIC countries, strong growth is forecast for China and India, where pharmaceutical sales are expected to more than double by 2016. Brazil and Russia also are expected to see positive growth.

Global **biotechnology** segment revenue was projected to have reached $262 billion in 2013, having increased at an average annual rate of 11 percent over the past five years. Over the next five years, the industry is expected to continue to prosper; revenue is forecast to reach $407.3 billion in 2018, with average annual growth projected to be 9.2 percent. With some exceptions, larger players are expected to continue pursuing low-risk strategies, including (1) buying out smaller firms to access successful research for commercial-ready technologies and (2) partnering with academic institutions. From a geographic standpoint, the Asia-Pacific region is investing significant capital to gain a strong foothold in the biotechnology segment.

The **medical technology** segment is expected to expand by 4.5 percent per year through 2018, taking in global sales of $455 billion. The segment's largest market is expected to be in vitro diagnostics — with predicted worldwide sales of $58.8 billion in 2018 — followed by cardiology. The fastest-growing market is neurology, which is projected to increase by 6.9 percent per year through 2018, reaching $8 billion. Diabetic care and orthopedics are expected to be the slowest-growing markets, expanding by 3.4 percent per year through 2018. Global medtech research and development (R&D) spending is expected to increase by 3.9 percent to $26.7 billion in 2018. The overall R&D investment rate is expected to be about 5.9 percent of sales in 2018, slightly down from 6.1 percent in 2012.

Despite encouraging economic and demographic trends, life sciences companies' growth prospects are being tempered by a number of challenging marketplace and enterprise issues:

- Navigating health care reform.
- Delivering innovation and value.
- Complying with regulatory changes.
- Operating in a more connected world.

To learn more about these macro issues, suggested considerations for stakeholders, and activity in specific geographic markets, see Deloitte's *2014 Global Life Sciences Outlook: Resilience and Reinvention in a Changing Marketplace*.

[1] This section was adapted from Deloitte's *2014 Global Life Sciences Outlook: Resilience and Reinvention in a Changing Marketplace*. Please refer to that publication for references and sources.

U.S. Market Update[2]

The year is expected to be a positive one for U.S. life sciences companies as they continue to enhance their understanding of the U.S. Affordable Care Act (ACA), improve their capitalization of emerging market opportunities, and incorporate real-world evidence into their strategic thinking and decision making.

The Economist Intelligence Unit projects that the U.S. pharmaceutical market, the world's largest at $396 billion in 2011, will increase by 6.4 percent annually through 2016. Demographics and disease trends will boost drug consumption, while the expansion of insurance coverage to millions of uninsured Americans under the ACA (via health insurance exchanges and Medicaid expansion) is forecast to increase revenue for drug makers. However, ACA-related pharmaceutical sector fees, a new medical device tax, and lower government drug prices could negatively affect growth. The FDA's continued work to finalize a biosimilars pathway is also a concern.

The current administration's policies are playing a key role in transforming the U.S. health care marketplace and shaping the life sciences sector's short- and long-term planning. The Department of Health and Human Services is hoping to accelerate the implementation of key reform elements, while Congress is working on driving funding appropriations.

The landscape for U.S. health care providers is also changing — physician-hospital consolidations are becoming more common, and the influence of combined purchasing departments is increasing. As a result, life sciences companies are employing new business models that recognize the power of decision makers in product pricing and selection.

To become more competitive, life sciences companies will need to shift their focus from competing on volume to competing on value. To achieve this objective, such companies will need a robust comparative effectiveness strategy and a fact-based evidence program that supports current commercial activities, informs late-stage clinical development, and provides forward visibility of the strategic needs to grow the business.

[2] This section was adapted from Deloitte's *2014 Global Life Sciences Outlook: Resilience and Reinvention in a Changing Marketplace*. Please refer to that publication for references and sources.

SEC Updates

SEC Comment Letter Trends

The Sarbanes-Oxley Act of 2002 requires the SEC staff to review every issuer's disclosures, including financial statements, at least once every three years. The staff's comments and registrants' responses are posted on the SEC's Web site and provide valuable insight into common comment themes. Registrants can incorporate a review of the comments into their financial reporting processes to help improve their financial statements and disclosures. The staff routinely comments on matters related to financial statement accounting, disclosure, and presentation.

The SEC staff's comments to registrants in the life sciences industry have primarily focused on (1) collaborative arrangements, (2) revenue recognition, (3) disclosure considerations (concerning R&D expenses and patents), (4) business combinations, and (5) income taxes.

The staff has also asked life sciences registrants to explain (1) how their accounting and reporting for a loss contingency complies with the recognition, measurement, and disclosure requirements in ASC 450[1] and (2) how their segment disclosures comply with ASC 280's requirements for disclosures that are disaggregated by products and services, geography, or major customer. For further discussion of loss contingencies and segment disclosures, see the Contingencies and Segment Reporting sections of Deloitte's *SEC Comment Letters — Including Industry Insights: Constructing Clear Disclosures* (the "annual comment letter publication").

Collaborative Arrangements

Examples of SEC Comments

- Please address your consideration of . . . ASC 808-10-45 in determining the appropriate accounting [for your collaborative arrangements]. For any significant agreements, please discuss the specific terms of the agreements and how you determined the appropriate accounting treatment for these agreements based on their terms. Please also provide the additional disclosures called for by . . . ASC 808-10-50, which should include the income statement classification and corresponding amounts attributable to transactions arising from collaborative arrangements for each period presented.
- Please refer to ASC 808-10-50-1 and provide proposed disclosure to be included in future filings for your collaboration agreement with [Company A] to address the following:
    - The rights and obligations of each party;
    - For each significant deliverable, whether or not it is a separate unit of accounting and the basis for your conclusion;
    - The accounting policy for each unit of accounting including pattern and period of recognition; and
    - The income statement classification of amounts recorded, other than the up-front payment.

Biotech and pharmaceutical companies often enter into collaborative arrangements. ASC 808-10 provides guidance on the income statement presentation, classification, and disclosures related to collaborative arrangements but "does not address recognition or measurement matters related to collaborative arrangements, for example, determining the appropriate units of accounting, the appropriate recognition requirements for a given unit of accounting, or when the recognition criteria are met." As a result, the SEC staff often asks registrants about the nature of, and accounting for, their collaborative arrangements and has continued to ask industry registrants about their basis for such accounting under U.S. GAAP. Recently, the staff's inquiries to registrants have focused on:

- The activities within the scope of their collaborative arrangements — for example, the basis for a conclusion that an arrangement is collaborative when it begins after the FDA approves a product for sale (e.g., because the collaborative arrangement does not include initial research activities).
- The model under which collaborative arrangements are, or should be, accounted for (e.g., an ASC 605 revenue recognition model or a cost reimbursement model).

[1] For titles of *FASB Accounting Standards Codification* (ASC) references, see Deloitte's "Titles of Topics and Subtopics in the *FASB Accounting Standards Codification*."

- The identification of, and allocation of consideration to, activities within the scope of a collaborative arrangement that represent true vendor-customer activities. In a collaborative arrangement, each party to the arrangement assumes a proportionate share of risks and a vendor-customer relationship therefore does not exist. Even if the registrant concludes that it is a party to a collaborative arrangement, however, there may be circumstances in which certain elements of the arrangement represent activities that are similar to those in a vendor-customer relationship. Accordingly, the SEC staff has sought to understand the registrant's process for identifying, and allocating consideration to, such activities.

Consequently, the SEC staff has requested enhanced disclosures about registrants' collaborative arrangements, especially a clear description of material terms such as (1) each party's rights and obligations under the arrangement, (2) potential payments, (3) the existence of royalty provisions, and (4) duration and termination provisions. In addition, the staff has commented on registrants' disclosures about all material amounts paid and received to date under each arrangement and how each payment was accounted for — specifically, the separation, allocation, recognition, and classification principles used.

Further, the SEC staff may ask registrants to file a material collaborative arrangement as an exhibit to their filing in accordance with Regulation S-K, Item 601(b)(10). For more information, see the Material Contracts section of Deloitte's annual comment letter publication.

Revenue Recognition

Examples of SEC Comments

- Please provide us with a description of your deliverables and units of accounting for these arrangements. Confirm how your accounting policy complies with paragraphs 25-3 to 25-6 of FASB ASC 605-25 and specifically address how each unit of accounting complies with 25-5(a) and 25-5(c) of that literature. Please also revise future filings to clearly identify the deliverables included in each separate unit of accounting and provide us with a copy of your proposed revised policy.
- You disclose that your agreement provides for additional payments . . . based on the achievement of certain development and regulatory events. Please revise your disclosure to include a description of the significant development and regulatory milestones and the related contingent consideration as required by ASC 605-28-50-2.b. and include the disclosures required by ASC 605-28-50-2.c. and d.

The SEC staff often asks registrants in the life sciences industry to expand or clarify their disclosures about multiple-element arrangements. At the 2012 AICPA Conference, the SEC staff described a typical multiple-element arrangement in which a vendor licenses intellectual property to a customer. The staff suggested that registrants could improve their required disclosures about the nature and terms of such arrangements by (1) separating the description of the obligations and rights from the discussion of how they were accounted for, (2) ensuring that this description is complete (i.e., that all material terms are disclosed), and (3) precisely describing the rights conveyed by the license. In addition, the staff reminded registrants that they should explicitly identify each deliverable in the arrangement and explain why it represents (or does not represent) a separate unit of accounting. The staff also suggested that registrants could improve their disclosures about the relative selling price method of allocating arrangement consideration by (1) quantifying the total arrangement consideration to be allocated, (2) identifying the amount of consideration allocated to each unit of accounting, and (3) explaining how the estimated selling price for each unit was determined (including the significant assumptions used).

The SEC staff also comments on disclosures about milestone recognition under ASC 605-28. When such disclosures apply, the staff will review filings to determine whether they contain the following disclosures outlined in ASC 605-28-50-2:

a. A description of the overall arrangement

b. A description of each milestone and related contingent consideration

c. A determination of whether each milestone is considered substantive

d. The factors that the entity considered in determining whether the milestone or milestones are substantive

e. The amount of consideration recognized during the period for the milestone or milestones.

For more information about multiple-element arrangements and other revenue-related considerations, see the Revenue Recognition section of Deloitte's annual comment letter publication.

Registrants in the life sciences industry will often make adjustments for milestone payments when determining non-GAAP income. For a discussion of this topic, see the Non-GAAP Financial Measures section of Deloitte's annual comment letter publication.

Disclosure Considerations

R&D Expenses

Example of an SEC Comment

We believe disclosing the cost of each of your key development programs is helpful to an understanding of the company's use of resources. In this regard, please revise your [disclosure] to separately disclose your external R&D costs for each of your key development programs. In addition, separately disclose your internal R&D expense by the nature of the expense (i.e. facilities, employees, general overhead, etc.)

The SEC staff has asked life sciences registrants to expand their disclosures about internal R&D expenses and estimated future expenses beyond those required under ASC 730-10. In addition to disclosing the types of activities and elements included in R&D expenses and the amount of R&D expenses incurred during each reporting period, registrants may be asked to revise their MD&A and business sections to include information about each major R&D project. If registrants do not maintain information about R&D costs by project or program, they may be asked to explain why.

Registrants must carefully consider whether such projects are significant enough to warrant disclosure and whether the timing of the costs associated with the projects can be reasonably estimated. Registrants involved in late-stage clinical trials should consider expanding their disclosures about such projects to reflect the uncertainty of ultimate regulatory approval and commercial success.

The SEC staff may also ask a registrant to include, in its contractual obligations table in MD&A, commitments to make payments for R&D contractual relationships. See the Management's Discussion and Analysis section of Deloitte's annual comment letter publication for more information about the contractual obligations table.

Patents

Example of an SEC Comment

Your disclosure . . . indicates that you are losing patent exclusivity in 2013 and 2014 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.

The SEC staff has also regularly commented on life sciences registrants' disclosure of patents, particularly on the patent exclusivity of their products and the impact of such exclusivity on revenues and overall operations. Patent expiration and challenges can affect not only a registrant's current-period earnings but also its future operations and liquidity, particularly if the patents are for core products. Registrants should consider the guidance in Regulation S-K, Items 101 and 503(c), respectively, on (1) disclosing patent information in the business section of their periodic filings and (2) discussing patent expiration and challenges as possible risk factors in their annual reports. In addition, the SEC staff has requested information on the subject matter and jurisdiction of a registrant's patents.

Business Combinations

Examples of SEC Comments

- Please provide us a summary of the analysis you performed for your acquisition of the licensing rights to market [Product X] outside the U.S. that supports your conclusion the inputs and/or processes acquired qualify as a business.
- Please explain to us your basis for concluding that the estimated useful life of the [Company A] amortizable intangibles was a weighted average of [X] years. Please breakout this analysis between customer relationships and patents and technology.

Because business combinations in the life sciences industry are common, the SEC staff frequently comments on this topic. For example, the staff has asked registrants about their evaluation of whether a certain transaction constitutes a business combination under ASC 805. In addition, the staff has asked registrants how they determined the useful life of their intangible assets. Because the intangible assets acquired are typically the patent rights to a product or potential product, most life sciences companies begin their analysis by considering the patent life of the underlying product. However, useful life could be affected by other factors, such as the risk of competition from branded or generic products before the registrant's patent expires or a high barrier to market entry even after the registrant's patent expires. Therefore, the staff has asked registrants to provide additional disclosures that explain the basis for their conclusions about their intangible assets' useful lives. For additional considerations, see the Business Combinations section of Deloitte's annual comment letter publication.

Income Taxes

Life sciences companies often have manufacturing and distribution sites, as well as holding company subsidiaries, domiciled in countries with favorable tax rates. If a life sciences registrant discloses that it will reinvest undistributed earnings of its foreign subsidiaries indefinitely, the SEC staff is likely to examine the registrant's liquidity disclosure to determine whether its cash holdings are sufficient to meet its long- and short-term liquidity needs. Therefore, the disclosures in the liquidity section of the MD&A about how the registrant plans to meet its funding obligations should be clear and robust. See the Income Taxes and Uncertain Tax Positions section of Deloitte's annual comment letter publication for additional information.

Accounting Hot Topics

Accounting for Collaborative Arrangements

As life sciences entities continue to adapt to an ever-changing marketplace, some may increasingly look to enter into or expand collaborations with third parties for the development or commercialization of certain drug candidates or medical products in an effort to share in both the costs and risks associated with such activities.

In collaborations, the parties may allocate responsibility for individual activities to each other or share the responsibility for one or more activities under a joint operating arrangement. Joint operating activities may involve the joint development and ultimate commercialization of intellectual property related to a potential new drug candidate, R&D, marketing (including promotional activities and physician detailing), general and administrative activities, manufacturing, and distribution activities. On the basis of contractually defined terms, the participants share in the profits or losses associated with these joint activities.

Such arrangements are often complex and can vary significantly in scope, terms, and conditions as well as risk mitigation objectives. The following are common forms of these arrangements:

- *Codevelopment and comarketing arrangements* — Joint operating agreements in which both parties to the agreement assume roles and responsibilities.
- *Copromotion arrangements* — Agreements in which companies partner together and use each company's commercial capabilities and experience to promote a product (owned by one of the parties) in various markets.

Determining the Accounting Treatment

When an entity enters into a collaboration, management must consider whether the arrangement meets the U.S. GAAP definition of a collaborative arrangement to determine whether the arrangement is subject to specific requirements of ASC 808. The legal characterization of an arrangement (e.g., as a collaboration or a collaborative arrangement) does not necessarily cause it to meet the definition of a collaborative arrangement under U.S. GAAP.

ASC 808-20 defines a collaborative arrangement as an arrangement that involves a joint operating activity and that includes two (or more) parties that are both:

- "[A]ctive participants in the activity."
- "[E]xposed to significant risks and rewards dependent on the commercial success of the activity."

On the basis of these criteria, some types of collaborations in the industry may not meet the definition of a collaborative arrangement and therefore would not be within the scope of ASC 808. For example, certain arrangements, in which one party solely provides financial resources for an endeavor and is generally not an active participant, would not meet the definition of a collaborative arrangement. Alternatively, arrangements between two parties that involve codevelopment, comarketing, or copromotion activities, as well as the sharing of risks and rewards based on the success of such activities, would generally meet the definition of a collaborative arrangement.

A collaboration can begin at any point in the life cycle of an endeavor (e.g., during the R&D phase or after a drug has been commercially launched). The facts and circumstances associated with the arrangement will dictate whether the parties (1) represent active participants and (2) are exposed to significant risks and rewards.

ASC 808-10-15-8 cites the following examples of situations in which active participation may exist:

- "Directing and carrying out the activities of the joint operating activity."
- "Participating on a steering committee or other oversight or governance mechanism."
- "Holding a contractual or other legal right to the underlying intellectual property."

In addition, ASC 808-10-15-11 lists circumstances that might indicate that participants are not exposed to significant risks and rewards:

- "Services are performed in exchange for fees paid at market rates."
- "A participant is able to exit the arrangement without cause and recover all (or a significant portion) of its cumulative economic participation to date."
- "Initial profits are allocated to only one participant."
- "There is a limit on the reward that accrues to a participant."

Further, according to ASC 808-10-15-12, an entity should also consider other factors when evaluating participants' exposure to significant risks and rewards, including (1) "[t]he stage of the endeavor's life cycle" and (2) "[t]he expected duration or extent of the participants' financial participation . . . in relation to the endeavor's total expected life or total expected value."

For collaborations that meet the definition of a collaborative arrangement, ASC 808 provides guidance on income statement presentation, classification, and disclosures. However, ASC 808 does not address recognition or measurement matters, such as (1) determining the appropriate unit of accounting or (2) when the recognition criteria are met. Thus, even when a collaboration is within the scope of ASC 808, companies must look to other GAAP (possibly by analogy) to determine the appropriate recognition and measurement for the activities subject to the arrangement.

An entity's accounting for a collaborative arrangement may also depend on whether there are any activities under the arrangement for which the entity and the counterparty have a customer-vendor relationship. For example, as part of a collaboration arrangement for which a biotechnology company and pharmaceutical company agree to coproduce and commercialize a newly approved drug, the biotechnology company may also agree to provide R&D services to the pharmaceutical company that represent the biotechnology company's ongoing major or central operations.[1] In such cases, the biotechnology company would apply revenue recognition guidance when recognizing and measuring the R&D services because the pharmaceutical company is deemed a customer for this element in the overall collaboration arrangement.

Income Statement Presentation Considerations

When determining the appropriate income statement presentation of amounts recorded as a result of a collaborative arrangement, companies will need to separately evaluate (1) transactions with third parties outside of the arrangement and (2) transactions between collaboration participants. ASC 808 requires that collaboration participants report costs incurred and revenue generated from transactions with third parties in each participant's respective income statement in accordance with the principal/agent guidance in ASC 605-45. The participant in the collaboration arrangement that is deemed the principal participant for a given transaction should record the transaction on a gross basis in its financial statements, notwithstanding the presence of cost sharing or cost allocation of such amounts based on the terms of the agreement.

Participants also need to evaluate the appropriate income statement presentation for payments between the collaboration partners (e.g., as a result of expense reimbursements or profit sharing). When such payments are within the scope of other authoritative accounting literature, entities should apply the income statement classification requirements by using the relevant provisions of that literature. If the payments are not within the scope of other authoritative accounting literature, the income statement classification for the payments is based on an analogy to authoritative accounting literature or — if there is no appropriate analogy — a reasonable, rational, and consistently applied accounting policy election.

[1] FASB Concepts Statement No. 6, *Elements of Financial Statements*, states that "[r]evenues are inflows or other enhancements of assets of an entity or settlements of its liabilities (or a combination of both) from delivering or producing goods, rendering services, or other activities that constitute the entity's ongoing major or central operations."

Collaborative arrangements are often complex and can vary significantly depending on their structure, terms, and conditions. The determination of whether an arrangement is within the scope of ASC 808 must occur at the inception of the arrangement, but such a determination should also be reevaluated whenever there is a change in roles or exposure to risks and rewards. Further, it is clear that these arrangements will continue to be very common in the industry and that the nature and extent of collaborative efforts and terms will evolve further. Companies may need to revisit their accounting and disclosures frequently to ensure that they are sufficiently transparent and useful to readers and investors.

AICPA's Guide on Acquired In-Process Research and Development Assets

In December 2013, the AICPA released a new accounting and valuation guide[2] containing nonauthoritative guidance, best practices, and illustrative examples related to "the initial and subsequent accounting for, valuation of, and disclosures related to acquired in-process research and development (IPR&D) assets."

The guide updates the AICPA's 2001 practice aid[3] on this topic to reflect significant U.S. GAAP changes that have affected the accounting for IPR&D, such as new requirements for measuring fair value under ASC 820 and changes in the accounting for business combinations under ASC 805. The AICPA's Web site describes the guide's key topics as follows:

- Initial and subsequent accounting for IPR&D assets acquired in a business combination and an asset acquisition.
- Key accounting considerations such as "used in R&D activities" criteria, unit of account, defensive IPR&D assets, useful life of completed intangible assets used in R&D activities, and elimination of core technology concept.
- Detailed information on subsequent Day 2 accounting for acquired IPR&D assets, including such issues as determining useful life, amortization, and impairment testing.
- Step-by-step guidance on how to measure fair value of IPR&D assets acquired in a business combination, asset acquisition, or for impairment testing and measurement purposes, including detailed discussions and examples of how to apply multiperiod excess earnings method, relief from royalty method and decision tree analysis.
- Comprehensive example which illustrates using the relief from royalty method to value trade name and patents, the "with and without" method to value customer relationships, and the multiperiod excess earnings method to value developed technology and IPR&D.
- Detailed discussion of steps to derive, prepare, and analyze the prospective financial information for IPR&D assets.

The guide provides life sciences entities with useful information on accounting for IPR&D assets acquired in M&A transactions. M&A activity is already integral to the growth strategies of many life sciences companies, and more deal activity is expected as companies seek to replenish their pipelines, enhance their core businesses, and take advantage of new growth prospects.

Initial Recognition of IPR&D Assets

As discussed in the sections below, the guide covers several key aspects of the initial recognition of IPR&D assets in a business combination.

[2] AICPA Accounting and Valuation Guide, *Assets Acquired to Be Used in Research and Development Activities*. The guide is available for purchase on the AICPA's Web site.

[3] AICPA Practice Aid, *Assets Acquired in a Business Combination to Be Used in Research and Development Activities: A Focus on Software, Electronic Devices, and Pharmaceutical Industries*.

Used in R&D Activities

The guide indicates that an asset to be "used in R&D activities" by the acquirer is distinguishable from other acquired assets and describes four categories of assets that meet this criterion: (1) assets related to an acquiree's R&D efforts that the acquirer will continue; (2) defensive assets (i.e., assets used to defend the value of other intangible assets used in R&D activities) that "the reporting entity intends to hold (or lock up) to prevent others from obtaining access to the asset"; (3) assets that the reporting entity intends to outlicense (or the acquiree has already outlicensed) "but plans to play an active role" in developing; and (4) "assets that the reporting entity plans to temporarily idle." Idled assets differ from defensive assets in that idled assets "do not contribute to an increase (or maintenance) in the value of the reporting entity's other assets."

Attributes of an Acquired IPR&D Project

The guide states that "an acquired IPR&D project will generally satisfy the definition of an asset" and that "an acquired IPR&D project will commonly be identifiable." Further, the guide indicates that there should be persuasive evidence that the asset has **substance** (the acquired company has performed activities that (1) constitute more than insignificant efforts, (2) meet the definition of R&D under ASC 730-10, and (3) result in creation of value) and is **incomplete** (risks remain or certain regulatory approvals are pending as of the acquisition date).

Unit of Account

The guide indicates that when determining the unit of account, companies may consider the following factors (not all-inclusive):

- "The phase of development of the related IPR&D project."
- "The nature of the activities and costs necessary to further develop the IPR&D project."
- "The risks associated with further development of the related IPR&D project."
- "The amount and timing of benefits expected to be derived in the future from the developed asset(s)."
- "The expected economic life of the developed asset(s)."
- "Whether there is an intent to manage costs for the developed asset(s) separately or on a combined basis in areas such as strategy, manufacturing, advertising, selling, and so on."
- "Whether the asset, whether as an incomplete IPR&D project or when ultimately completed, would be transferred by itself or with other separately identifiable assets."

In practice, some life sciences companies have considered units of account on a global basis while others have viewed units of account by region, depending on the type of product or asset. Life sciences companies should carefully consider their own facts and circumstances when determining the unit of account.

Subsequent Accounting for IPR&D Assets

The guide observes that, after a business combination, management may (1) continue internal R&D efforts associated with the assets or collaborate with another party in R&D efforts, (2) dispose of the assets through sale, (3) outlicense the assets, (4) decide to temporarily postpone further development, or (5) abandon R&D efforts, each of which may have specific accounting implications. Further, upon completion of an IPR&D project, the asset is generally recharacterized from an indefinite-lived IPR&D asset to an asset resulting from R&D activities. The guide contains the following table (in paragraph 4.07) illustrating the differences between accounting for an indefinite-lived IPR&D asset and accounting for an asset resulting from R&D activities:

	Indefinite-Lived IPR&D Asset	Asset Resulting From R&D Activities
Amortization period	N/A	Period over which the asset is expected to contribute directly or indirectly to the future cash flows of the entity.
Amortization method	N/A	Reflects the pattern in which economic benefits of the intangible asset are consumed or otherwise used up. If that pattern cannot be reliably determined, a straight-line amortization method should be used.
Model and timing for impairment testing	Test for impairment in accordance with ASC 350-30-35-18 and 35-19. Testing required annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. Testing for impairment once the associated R&D efforts are completed or abandoned and, therefore, the indefinite-lived IPR&D asset is determined to have a finite life. An entity may first perform a qualitative assessment to determine whether it is necessary to perform the quantitative impairment test. Impairment loss is recognized if the carrying amount of the asset exceeds its fair value.	Test for impairment in accordance with ASC 360-10-35-17 through 35-35. Testing required whenever events or changes in circumstances indicate that the carrying amount of an asset resulting from R&D activities (asset group) may not be recoverable. Impairment loss is recognized if the carrying amount of the asset (asset group) is not recoverable and exceeds its fair value.

Life sciences companies may encounter various challenges in performing an impairment analysis of IPR&D assets. However, they may consider the following questions when performing a qualitative analysis:

- *Regulatory considerations* — Has the product received approval in any markets since the previous analysis? Are there changes to the regulatory environment or matters suggesting any loss of value for the asset (e.g., FDA communication suggesting delay)? Have there been any negative results since the previous analysis either internally or through public sources (clinicaltrials.gov)? What is the status of clinical testing, and is the estimated product launch date still achievable? Is there any delay in the next expected regulatory milestone or indication according to plan?
- *Commercial and legal considerations* — Are there any major changes in the competitive landscape for the IPR&D product (e.g., competitive product launched or filed/delayed, price decrease of existing product)? Is the projected market share still realistic? Have there been any changes to the patents or other exclusive rights? Are there changes to the commercial or legal environment that may suggest any loss of value for the asset?
- *Financial and strategic considerations* — Are there future strategic plans to continue/discontinue clinical testing? Is there any change in the amount and timing of expected future R&D costs? Is there any change in the amount and timing of projected operating costs or projected revenues? Is there any change in the estimated probability of technical and regulatory success? Is there sufficient funding available to complete the development of and launch the product? Are there any other financial or strategic reasons that may suggest loss of use or another decline in value?

Valuation of IPR&D Assets

The guide describes best practices for measuring the fair value of IPR&D assets and discusses relevant considerations related to (1) applying the fair value measurement concepts in ASC 820 and (2) identifying appropriate valuation methods and applying them to IPR&D. The guide includes a comprehensive example that illustrates application of the concepts discussed.

Disclosures

The guide notes that the disclosures that entities are required to include about IPR&D assets are limited but provides general considerations for management to evaluate when determining the nature and extent of related disclosures, as well as sample disclosures. In addition, the guide indicates that the following points could influence management's determination of which IPR&D-related disclosures to include in MD&A:

- Acquired IPR&D projects represent a known event that may produce uncertainty that could reasonably be expected to materially affect future operating results due to additional R&D expenses expected to be incurred to complete the projects and changes in revenue and profitability from changes in the product sales mix.
- Acquired IPR&D projects may represent a material demand on liquid resources to fund completion of the projects.
- Qualitative information about management's objectives in material acquisitions of businesses and intangibles may be helpful in understanding the financial statements "through the eyes of management."
- The nature of certain businesses may be high risk and require investment in a large number of projects for achieving a successful portfolio of approved products. As such, many of the early-stage acquired IPR&D projects could become impaired and be written off at some time in the future.

R&D Funding Arrangements

The need for new sources of capital in the life sciences industry has led to innovative R&D funding arrangements with diverse terms and conditions. In these arrangements, passive third-party investors often provide funds to offset the cost of R&D programs in exchange for milestone payments or other forms of consideration (typically sales-based royalties) that are contingent on the successful completion of such R&D programs and the related approval for the compound(s) being developed. Typically, life sciences companies would retain all intellectual rights to any compounds resulting from the R&D efforts. The investor would not receive repayment or any other forms of consideration if the compound or compounds subject to the R&D arrangement are not successfully developed and commercialized.

Determining the Accounting Treatment

A critical question related to the accounting for such arrangements is whether there is a liability to recognize in connection with an investor's contributions. ASC 730-20-25-4 states, "To conclude that a liability does not exist, the transfer of the financial risk involved with research and development from the entity to the other parties must be substantive and genuine." This paragraph further gives examples of circumstances in which risk has not been transferred:

- "The entity guarantees, or has a contractual commitment that assures, repayment of the funds provided by the other parties regardless of the outcome of the research and development."
- "The other parties can require the entity to purchase their interest in the research and development regardless of the outcome."
- "The other parties automatically will receive debt or equity securities of the entity upon termination or completion of the research and development regardless of the outcome."

Even in the absence of an explicit requirement for repayment, there may be other circumstances in which the entity will most likely bear the risk associated with the failure of the R&D activities. ASC 730-20-25-5 states, "If those conditions suggest that it is probable that the entity will repay any of the funds regardless of the outcome of the research and development, there is a presumption that the entity has an obligation to repay the other parties." Further, such a presumption "can be overcome only by substantial evidence to the contrary." ASC 730-20-25-6 describes the following circumstances as leading to the presumption that the entity will repay the other parties:

- "The entity has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development."
- "The entity would suffer a severe economic penalty if it failed to repay any of the funds provided to it regardless of the outcome of the research and development."
- "A significant related party relationship between the entity and the parties funding the research and development exists at the time the entity enters into the arrangement."
- "The entity has essentially completed the project before entering into the arrangement."

Companies in the life sciences industry typically assign probability of technical and regulatory success (PTRS) rates to development-stage compounds on the basis of estimates of the likelihood that such compounds eventually will be approved by the FDA or other regulatory organizations. Because PTRS rates are often used to determine resource and capital allocation strategies, it is often important for companies to consider the PTRS rate for a respective compound in evaluating whether a "substantive and genuine" risk transfer has occurred and whether repayment is "probable." However, there is not a "bright line" PTRS rate for whether repayment should be considered probable. Therefore, companies should consider all facts and circumstances in determining whether repayment is likely to occur.

In practice, investors often desire certain terms and conditions that reduce risk. However, such terms and conditions can complicate an analysis under 730-20 and could ultimately trigger liability accounting for an R&D funding arrangement. Various deal structures favored by investors can therefore raise significant doubt regarding whether a transfer of risk has occurred:

- *Multiple products ("the basket approach")* — An investor's risk is reduced by increasing the number of covered products; such circumstances must be carefully evaluated, and other factors (e.g., number of products, stage of development of each, payment mechanisms) would be important.
- *Substitution rights* — An investor's risk is reduced by the right to replace a failed molecule or project in the R&D arrangement with one or more other molecules or projects that still have the potential to be commercialized.
- *Royalty rates based on commercialization sequence* — An investor's risk is reduced by assigning a royalty rate (typically the highest) to the first successful outcome within a portfolio of products, with lower rates assigned to each successive outcome that has no direct economic correlation to product market potential or probability of success.
- *Rights to unrelated revenue streams* — An investor's risk is reduced by incorporating rights to cash flows from an unrelated revenue stream, such as a royalty on a separate and distinct product for which the investor did not fund the related R&D. If cash flows associated with an unrelated revenue stream (i.e., milestone or royalty payments related to sales of developed products unrelated to the compounds that were subject to the R&D funding arrangement) are included in accordance with the terms of the arrangement, the guidance in ASC 470-10-25 on sales of future revenue streams should be considered. Such guidance may similarly require companies to reflect such funding payments as debt in the financial statements.

Typically, a separate legal entity is not created for the performance of the R&D funding arrangements. However, if a legal entity is created for the purposes of the R&D funding arrangement, the guidance in ASC 730-20 may still apply, in addition to consolidation considerations.

Because of the inherent uncertainty associated with compounds in the R&D process, life sciences companies often perform clinical trials, hoping to obtain approval to treat multiple disease types (commonly referred to as "indications" or "labels"). While such R&D programs are often developed specifically to determine the effectiveness of a compound to treat a particular indication, companies typically are not able to track sales of a product by indication when the product has been granted approval for more than one indication. Therefore, in light of the guidance above, companies should assess whether sales-based royalties to be paid on overall product sales should be considered an unrelated revenue stream if the R&D funding arrangement was specific to certain indications and did not include R&D activities for all indications for which the respective compound is approved and marketed. This evaluation is especially important if the compound is already approved and marketed for certain indications.

In addition, life sciences companies often conduct R&D programs to obtain regulatory approval in certain jurisdictions (or markets). If an R&D funding arrangement is specifically related to R&D studies to obtain approval in a certain jurisdiction, but the arrangement calls for future sales-based royalties on global product sales (if and when such a compound is approved), companies should evaluate whether such sales-based royalties to be paid on overall product sales should be considered an unrelated revenue stream. As above, this evaluation is particularly important if the compound is already approved and marketed in certain jurisdictions.

Determining Whether an Asset Group Constitutes a Business

In accounting for M&A activities, life sciences entities must often carefully assess whether the net assets acquired in a transaction constitute a business. This determination governs whether the transaction is accounted for as a business combination or an asset acquisition. The differences between the accounting for a business combination and that for an asset acquisition are limited but can sometimes have a significant impact. The following are a few of those differences:[4]

- *Cost of the acquisition* — In a business combination, the fair value of the consideration transferred excludes the transaction costs; in an asset acquisition, transaction costs are generally included in the cost of the acquisition. In addition, contingent consideration in an asset acquisition is not accounted for in accordance with ASC 805-30-25-5 through 25-7 but in accordance with other applicable GAAP, such as ASC 450 and ASC 815.
- *Measuring the assets acquired and liabilities assumed* — In an asset acquisition, an entity allocates the cost of the transaction to the assets and liabilities acquired on the basis of their relative fair values and is not permitted to recognize any goodwill. Any excess of cost over the fair values of the net assets is allocated on a pro rata basis, typically to the acquired nonfinancial assets.
- *Recognition of intangible assets* — ASC 805 requires that assets acquired in a business combination that are used in R&D activities (i.e., in-process R&D) be initially recognized as indefinite-lived intangible assets and measured at fair value. In an asset acquisition, the cost of acquired intangible assets to be used in R&D activities, when these assets do not have an alternative future use, are charged to expense in accordance with ASC 730.

In the life sciences industry, the current focus on cash management, strategic portfolio reviews, and risk mitigation is giving rise to nontraditional deal structures. These variations can complicate the analysis of whether a transaction should be accounted for as a business combination.

[4] For a comprehensive discussion of the differences between an asset acquisition and a business combination, see Deloitte's *A Roadmap to Accounting for Business Combinations and Related Topics*.

Applying the Definition of a Business

ASC 805 defines a business as "[a]n integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants." ASC 805-10-55-4 through 55-9 provide implementation guidance (not all-inclusive) to help entities identify what constitutes a business. This guidance includes the following:

- *"A business consists of inputs and processes applied to those inputs that have the ability to create outputs. Although businesses usually have outputs, outputs are not required for an integrated set to qualify as a business."* When it is not clear whether an integrated set of assets and activities meets the definition of a business, it may be helpful to first identify all of the inputs, processes, and outputs that were acquired. If all of the inputs and processes necessary to create outputs were acquired, the set is likely to be a business.

- *"A business need not include all of the inputs or processes that the seller used in operating that business if market participants are capable of acquiring the business and continuing to produce outputs, for example, by integrating the business with their own inputs and processes."* Not all of the inputs and processes necessary to make outputs must be acquired for the set to qualify as a business. If the set can be easily integrated into a market participant's operations, or the missing inputs or processes can be readily acquired without significant delay or effort, the set may qualify as a business.

- *"An integrated set of activities and assets in the development stage might not have outputs. If not, the acquirer should consider other factors to determine whether the set is a business."* If the set is not yet producing outputs, it may still qualify as a business. Development-stage entities might not yet have outputs, but if the set has begun operations, has inputs and processes, and is following a plan to produce outputs and reach customers, it is likely to qualify as a business too.

- *"In the absence of evidence to the contrary, a particular set of assets and activities in which goodwill is present shall be presumed to be a business. However, a business need not have goodwill."*

Although an entity must carefully analyze the facts and circumstances in determining whether an asset group qualifies as a business, the following examples may help illustrate this determination:

Example 1

Pharma Co. enters into a worldwide license, manufacturing, and distribution agreement with Biotech Co. for a compound in clinical development. Pharma Co. receives the right to manufacture, market, and distribute the compound in perpetuity if and when regulatory approval is obtained; however, Pharma Co. does not acquire any tangible manufacturing assets, employees, or contract manufacturing or research arrangements.

Pharma Co. identifies numerous missing elements for producing outputs, including (1) inputs (e.g., regulatory-approved compound, equipment and facilities, personnel) and (2) processes (e.g., contract or other manufacturing). A market participant cannot acquire the missing inputs/processes to develop and produce the compound without significant delay or effort. Pharma Co. concludes that the group of assets is not a business.

Example 2

Pharma Co. enters into a worldwide license, manufacturing, and distribution agreement with Biotech Co. for an approved drug. Pharma Co. receives the right to manufacture, market, and distribute the newly developed drug in perpetuity and obtains manufacturing know-how and documentation from Biotech Co. However, Pharma Co. does not acquire any tangible manufacturing assets, employees, or contract manufacturing arrangements and expects that obtaining regulatory approval to manufacture the drug will take significant time.

Pharma Co. identifies numerous missing elements for producing outputs, including (1) inputs (e.g., regulatory-approved equipment and facilities, personnel) and (2) processes (e.g., standard operating procedures, contract manufacturing).

A market participant cannot acquire the missing inputs/processes to produce the developed drug without significant delay or effort. Pharma Co. concludes that the group of assets is not a business.

Example 3

Pharma Co. acquires a manufacturing plant. Acquisition of the plant includes the plant's tangible assets, employees, and business licenses/registrations. Pharma Co. intends to immediately modify the facility to produce active pharmaceutical ingredients (e.g., raw materials) instead of finished dosage forms (e.g., finished goods). Because of the planned modifications, Pharma Co. does not acquire the facility's existing customer contracts and will not continue to sell any of the products previously manufactured in the facility.

Pharma Co. concludes that the facility contains the elements necessary for producing outputs, including (1) inputs (i.e., tangible assets, intangible assets, employees) and (2) processes (i.e., the production of finished dosage forms). Pharma Co.'s intended use for the facility is not a factor — the assessment is from the perspective of a market participant. Because the plant was operating and producing outputs upon acquisition, a market participant could have acquired the plant and continued to operate it in that manner. Pharma Co. concludes that the group of assets is a business.

For entities in the life sciences industry, some of the more challenging aspects of analyzing a transaction include comparing the acquired inputs and processes with the inputs and processes that, together, are needed to produce outputs. Further, in the absence of key inputs and processes, entities must consider whether those inputs are already available to, or could be easily acquired by, a market participant.

Standard-Setting Developments

Revenue Recognition

The FASB and IASB have substantially completed redeliberations of their November 2011 revised exposure draft (ED) *Revenue From Contracts With Customers*. The ED, released by the FASB as a proposed Accounting Standards Update (ASU), outlines a single comprehensive model for entities to use in accounting for revenue and will supersede most current revenue recognition guidance.

The goal of the revenue recognition project is to clarify and converge the revenue recognition principles under U.S. GAAP and IFRSs and to develop guidance that streamlines and enhances revenue recognition requirements while also providing "a more robust framework for addressing revenue issues." The boards aim to improve the consistency of requirements, comparability of revenue recognition practices, and usefulness of disclosures.

The proposed ASU is based on a core principle under which an entity "shall recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services." In applying the proposed ASU's provisions to contracts within its scope, an entity would:

- "Identify the contract with a customer" (step 1).
- "Identify the separate performance obligations in the contract" (step 2).
- "Determine the transaction price" (step 3).
- "Allocate the transaction price to the separate performance obligations in the contract" (step 4).
- "Recognize revenue when (or as) the entity satisfies a performance obligation" (step 5).

The proposed ASU applies to all contracts with customers, except those that are within the scope of certain other topics (e.g., leases, insurance). The proposed ASU defines a customer as "a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities" but further indicates that a counterparty to a contract may not be a customer in arrangements in which there is a sharing of "risks and benefits of developing a product to be marketed."

A life sciences entity would need to assess whether the counterparty to any collaborative arrangement meets the definition of a customer when determining the applicability of the proposed ASU. Arrangements that are currently within the scope of ASC 808 involve the sharing of "significant risks and rewards"; thus, for associated activities accounted for under ASC 808, the counterparties are generally not likely to be viewed as customers. However, entities accounting for collaborative arrangements within the scope of ASC 808 sometimes look to guidance outside of ASC 808 for topics related to recognition and measurement. Therefore, the proposed ASU's principles regarding recognition and measurement may still affect the accounting for a collaborative arrangement that is not within the scope of the proposed ASU.

Recent Redeliberations

At a joint meeting in late 2013, the FASB and IASB reached tentative decisions on three open issues related to the proposed ASU.

Constraint on Estimates of Variable Consideration

The boards tentatively decided that an entity should include the amount of variable consideration in the transaction price only if it is probable[1] according to the FASB — or highly probable[2] according to the IASB — that a subsequent change in the estimate of the amount of variable consideration would not result in a significant revenue reversal. An entity would assess each source of variability separately and would be required to update the transaction price as of each reporting date to incorporate changes to its estimate of this "minimum amount" during the period.

As noted in their October 28 staff paper for the meeting, the boards also tentatively decided that the standard would "[i]nclude an exception that would preclude an entity from including in the transaction price an estimate of sales or usage-based royalties from licenses of intellectual property until the customer's subsequent sales or usage occur."

Implementation Guidance Associated With Applying the Revenue Standard to Licenses

The boards affirmed their previous decision that some licenses provide access to the entity's intellectual property (IP) as it exists at the time the customer accesses the IP, while other licenses provide a right to use the entity's IP at the time control is transferred to the customer. The boards tentatively decided to provide criteria for determining when a distinct license (i.e., a performance obligation) of IP is "dynamic" (i.e., the license gives the customer a right to access the IP because the nature of the rights obligates the customer to use the most recent form of the entity's IP).

The boards tentatively decided that a license would be considered dynamic if the following criteria are met:[3]

> a. The contract requires or the customer reasonably expects that the entity will undertake activities that significantly affect the intellectual property to which the customer has rights (that is, the intellectual property . . . is dynamic). . . .
>
> b. Those activities do not transfer a good or a service to the customer as those activities occur (that is, the activities are not accounted for as performance obligations).
>
> c. The rights granted by the license directly expose the customer to any positive or negative effects of the entity's activities that affect the intellectual property as and when the entity undertakes those activities and the entity expects that the customer entered to the contract with the intention of being exposed to those effects.

If these criteria are met, control of the license is transferred over time (i.e., revenue is recognized over time). If the criteria are not met, the license gives the customer a right to use the entity's IP and control is transferred at a point in time (i.e., revenue is recognized at a point in time).

Collectibility

The boards tentatively decided to remove the requirement that an entity must "intend to enforce" its rights under a contract. Instead, the proposed model introduces a collectibility threshold that precludes an entity from recognizing revenue unless it is probable[4] that the entity will collect the consideration it ultimately will be entitled to receive under the contract.

If a contract did not meet the aforementioned collectibility criteria at contract inception, an entity would, as outlined in the staff paper, "reassess the contract at each reporting date to determine whether the criteria . . . are subsequently met." After meeting the criteria, an entity would not perform the reassessment "unless there is an indication of a significant change in facts and circumstances."

The boards also clarified that when facts and circumstances indicate that an entity intends to issue a price concession at contract inception, subsequent changes in that estimate are most likely changes in the transaction price (not impairment losses).

[1] ASC 450-20, *Contingencies: Loss Contingencies*, states that the term "probable" refers to a "future event or events [that] are likely to occur."

[2] Paragraph BC81 of IFRS 5, *Non-current Assets Held for Sale and Discontinued Operations*, states that "'highly probable' . . . impl[ies] the same probability as the FASB's phrase 'likely to occur.'"

[3] The boards outlined these criteria in the October staff paper.

[4] As stated in the October staff paper, "although [the term probable is] not defined in IAS 18 and IAS 11 it is defined elsewhere in IFRS to mean 'more likely than not.'"

These tentative decisions will have implications for entities in the life sciences industry and could cause the timing of revenue recognition under the new standard to differ from that in current practice. For example, the inclusion of variable consideration in the transaction price on the basis of a probability threshold could accelerate the recognition of milestone revenue; however, while such consideration would be included in the transaction price when the probability threshold is met (i.e., step 3), its recognition as revenue would still depend on how the consideration is allocated to the separate performance obligations (i.e., step 4) and whether the underlying performance obligation or obligations have been satisfied (i.e., step 5). In addition, life sciences entities will have to use judgment in determining whether a license arrangement represents a performance obligation that is satisfied over time or at a point in time — a distinction that could significantly affect the timing of associated revenues.

Disclosures

The proposed ASU significantly expands the current revenue recognition disclosure requirements. Entities would be required to disclose both quantitative and qualitative information about (1) the amount, timing, and uncertainty of revenue (and related cash flows) from contracts with customers; (2) the judgment, and changes in judgment, exercised in applying the proposal's provisions; and (3) assets recognized from costs to obtain or fulfill a contract with a customer.

Effective Date and Transition

For public entities, the new standard will be effective for reporting periods (fiscal and interim) beginning after December 15, 2016. The following three alternative adoption dates will be available to nonpublic entities:

- The effective date for public entities.
- Annual reporting periods beginning after December 15, 2016, including interim periods thereafter (i.e., same initial year of adoption as that for public entities, but nonpublic entities would be allowed to postpone adoption of the ASU during interim reporting periods in that year).
- Annual reporting periods beginning after December 15, 2017, including interim periods therein (i.e., one-year deferral).

Under U.S. GAAP, entities would not be permitted to early adopt the standard, although entities reporting under IFRSs would have the option of doing so. Further, entities would have the option of using either a retrospective transition approach (with certain practical expedients) or a modified approach to apply the new standard. Entities that choose retrospective application would also consider the requirements in ASC 250. According to the Summary of Board Decisions for the FASB's and IASB's February 20, 2013, joint meeting, under the modified approach, an entity would recognize "the cumulative effect of initially applying [the revenue standard] as an adjustment to the opening balance of retained earnings . . . in the year of initial application." Under the modified approach, the new standard would apply to contracts for which the entity has remaining performance obligations to fulfill as of the initial adoption date but would not apply to contracts that were completed (i.e., the entity has no remaining performance obligations to fulfill) before the initial adoption date. In the year of adoption, entities would also be required to disclose an explanation of the impact resulting from the adoption of the final standard as well as the financial statement line items and respective amounts that are directly affected by the standard's adoption.

Next Steps

The FASB and IASB are expected to issue a final revenue recognition standard in the first half of 2014.

Because the proposed revenue standard will replace a significant amount of authoritative literature, there may be a need for interpretive guidance. This could be particularly relevant for companies in industries that currently apply specialized revenue guidance under U.S. GAAP (e.g., software, construction, real estate). The AICPA has formed a number of industry-specific task forces to identify challenging implementation issues under the new guidance and to develop frameworks for assessing the issues, with a goal of minimizing diversity in practice when the new rules are implemented. The life sciences industry has not yet established a task force as part of the initiative, although life sciences industry members have actively participated throughout the standard-setting process.

Discontinued Operations

On April 2, 2013, the FASB issued a proposed ASU[5] that would substantially converge the definition of a discontinued operation under ASC 205-20 with that under IFRS 5. The proposal would also expand the disclosure requirements for disposals, including disclosures about individually material components that do not qualify as discontinued operations.

In addition to promoting convergence, the proposed guidance is intended to address concerns that (1) "too many disposals of assets qualify for discontinued operations presentation under the current definition, resulting in financial statements that are not decision useful" and (2) the "continuing involvement criterion is difficult to apply and does not result in consistent application."

Scope

The proposed guidance applies to all recognized noncurrent assets and to all disposal groups of an entity. The proposal would remove the current scope exceptions for certain assets, such as goodwill and equity method investments. The FASB notes that removing these scope exceptions would (1) improve convergence of U.S. GAAP and IFRSs and (2) result in the use of the proposed definition to evaluate all disposals to determine whether they would qualify for presentation as discontinued operations. Other than for entities that dispose of certain equity method investments, whose disposals could now qualify as discontinued operations, the FASB expects the effect of such scope changes to be limited.

Definition of a Discontinued Operation

The Board tentatively decided to modify the definition of a discontinued operation to specify that a component or a group of components of an entity should be reported as a discontinued operation if the following criteria, as outlined in the Summary of Board Decisions, are met:

1. The component or group of components has been disposed of, or is classified as held for sale, together as a group in a single transaction
2. The disposal of the component or group of components represents a strategic shift that has (or will have) a major effect on an entity's financial results. A strategic shift includes a disposal of:
    a. A separate major line of business,
    b. A separate major geographical area of operations, or
    c. A combination of parts of (a) or (b) that make up a major part of an entity's operations and financial results.

The Board also tentatively decided to (1) remove language about a single coordinated plan from the definition of a discontinued operation because it was confusing and (2) add examples to clarify what may constitute a major line of business or major geographical area of operations. Although the FASB removed the current continuing-involvement criterion from the proposed definition of a discontinued operation, disclosure about such status would still be required.

[5] See Deloitte's April 3, 2013, *Heads Up* for an overview of the proposed ASU.

Divestitures are common in the life sciences industry, particularly because some life sciences entities have recently sought to achieve greater specialization and focus in their business. Entities engaged in such restructurings may find that the proposal's threshold for presenting discontinued operations (i.e., one that is limited to strategic, material shifts and that does not depend on an assessment of continuing involvement) is more reasonable and practical to apply.

Disclosures

The proposed guidance requires entities to disclose additional information about discontinued operations. The Board believes that fewer disposals of components of an entity would be reported as discontinued operations under the proposed guidance and that financial statement users therefore would have less information about such disposals. As a result, the proposal expands the disclosure requirements for individually material components that do not meet the proposed definition of a discontinued operation.

Effective Date and Transition

The Board tentatively decided that entities would apply the new guidance prospectively. Public companies would apply it to annual periods beginning on or after December 15, 2014, and interim periods therein. Nonpublic entities would apply it to annual periods ending on or after December 15, 2015, and interim periods thereafter.

Next Steps

The FASB is expected to issue a final standard on discontinued operations in the first quarter of 2014.

Goodwill

On January 16, 2014, the FASB issued ASU 2014-02,[6] which offers eligible private companies a simplified alternative approach to accounting for goodwill. This alternative was initially developed by the Private Company Council (PCC) and ultimately endorsed by the FASB.

The ASU explains that during outreach performed by the PCC, "users of private company financial statements indicated that the goodwill impairment test performed today provides limited decision-useful information because most users of private company financial statements generally disregard goodwill and goodwill impairment losses in their analysis of a private company's financial condition and operating performance."

Simplified Accounting

On December 23, 2013, the FASB issued ASU 2013-12, which defines the term "public business entity." The definition establishes, in part, the scope of alternatives developed by the PCC. Specifically, entities that do not qualify as public business entities are eligible to elect the PCC alternatives as long as they satisfy any additional scope criteria those alternatives may include.

Under ASU 2014-02, private companies can elect simplified accounting for the following:

- *Amortization of goodwill* — Private companies can amortize goodwill on a straight-line basis over a useful life of (1) 10 years or (2) less than 10 years if they can demonstrate that a shorter useful life is more appropriate.
- *Frequency of impairment testing* — Private companies only need to test goodwill for impairment when a triggering event occurs rather than having to perform the test annually.

[6] See Deloitte's January 27, 2014, *Heads Up* for an overview of the ASU.

- *Method of impairment testing* — Private companies can make an accounting policy election to test goodwill for impairment at either the entity level or the reporting-unit level. In addition, ASU 2014-02 eliminates step 2 of the goodwill impairment test; as a result, private companies that elect the simplified accounting alternative would measure goodwill impairment as the excess of the entity's (or reporting unit's) carrying amount over its fair value (i.e., by using the measurement in step 1 of the goodwill impairment test under ASC 350-20).

While nonpublic life sciences companies that carry goodwill may find the PCC alternative appealing, they should be aware that if they register with the SEC later on (or include their financial statements in another entity's SEC filing as a result of a sale transaction), it is currently expected that the SEC would not permit the goodwill alternative in the SEC filing. Thus, the accounting alternative would need to be eliminated from the entity's historical financial statements.

Effective Date and Transition

If elected, the simplified goodwill accounting alternative in ASU 2014-02 must be applied prospectively to (1) goodwill existing as of the beginning of the period of adoption and (2) all new goodwill recognized in annual periods beginning after December 15, 2014, and in interim periods within annual periods thereafter. Private companies would commence amortization of goodwill existing as of the beginning of the period of adoption. Early application is permitted for any annual or interim period for which an entity's financial statements have not yet been made available for issuance. Upon adoption of the accounting alternative, an entity must make an accounting policy election to test goodwill for impairment at either the entity level or the reporting-unit level.

Next Steps

In connection with its endorsement of the goodwill alternative, the FASB added a project to its technical agenda to consider changes to goodwill accounting for public business entities and not-for-profit entities. The Board directed the FASB staff to research simplified goodwill accounting options, including (1) the PCC alternative; (2) the amortization of goodwill over its useful life, not to exceed a maximum number of years; (3) the direct write-off of goodwill; and (4) a simplified impairment test.

Many entities in the life sciences industry would be affected by an overall change to the accounting for goodwill. Those looking for relief from the current requirements are encouraged to keep apprised of this project and offer their input to the FASB when a proposed ASU is issued.

Appendixes

Appendix A — Deloitte Specialists and Acknowledgments

Specialists and Contacts

John Rhodes
Global Life Sciences Sector Leader, Deloitte Touche Tohmatsu Limited, &
Industry Professional Practice Director, Deloitte & Touche LLP
+1 973 602 6908
jorhodes@deloitte.com

Matt Riviello
Audit Partner, Deloitte & Touche LLP
+1 215 405 7774
mriviello@deloitte.com

Acknowledgments

In addition, we would like to thank the following Deloitte professionals for contributing to this document:

Teri Asarito
Lynne Campbell
Chris Chiriatti
Mark Crowley
Geri Driscoll
Jeffrey Ellis
Dennis Howell
Paul Josenhans
Michael Lombardo
Stephanie Poll
Joe Renouf
Lora Spickler-Alot
Stefanie Tamulis
Justin Truscott
Luanne Urbanowicz

Appendix B — Other Resources

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