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Life Sciences

Accounting and Financial
Reporting Update —
Including Interpretive
Guidance

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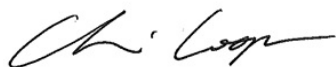
Foreword

March 2016

Growth in the life sciences sector — which comprises the pharmaceutical, biotechnology, and medical technology segments — is closely tied to economic and demographic drivers that fuel a continual transformation of the broader health care industry. Life sciences companies have demonstrated their ability to survive and thrive amid recent periods of economic recession, health care spending cutbacks, geographic market swings, and changing population profiles. If history is any indication, 2016 will again test the sector’s ability to adapt in an era of transformation.

At the same time, transformations in financial reporting present finance professionals of life sciences companies with unprecedented challenges. Changes to the accounting standards that affect revenue recognition and the definition of a business could significantly affect the accounting for transactions in the life sciences industry. While these changes are being evaluated, finance professionals must remain focused on complex areas of existing accounting standards related to revenue recognition, acquisitions and disposals, consolidation, contingencies, and financial statement presentation and disclosure.

We’re pleased to issue our seventh annual accounting and financial reporting update for the life sciences industry, which highlights each of these topics affecting the industry. 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. For a detailed analysis of industry issues and trends, see Deloitte’s *2016 Global Life Sciences Sector Outlook*.



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Revenue Recognition

Introduction

Many transactions in the life sciences industry must be carefully analyzed for revenue recognition purposes. Revenue recognition topics that are particularly relevant to life sciences entities include the SAB Topic 13¹ requirements (e.g., fixed or determinable sales price, collectibility is reasonably assured); the accounting for multiple elements; the ability to estimate returns; and the accounting for discounts, rebates, and incentives. Further, biotech and pharmaceutical firms may sometimes encounter complexities related to the milestone method of accounting, the proportional performance method of revenue recognition, principal-agent considerations, license fees, contingent revenue, and up-front payments. Meanwhile, medical device companies may have to analyze warranties, shipping terms, consignment sales, customer financing, and the potential applicability of lease and software revenue recognition requirements.



Life sciences entities also rely heavily on collaborative arrangements to leverage expertise and manage risk. In accounting for collaborative arrangements under ASC 808, entities often also apply the revenue recognition guidance — for example, when:

- Performing a principal-agent analysis for transactions with third parties.
- Determining the unit of account, measurement, and recognition of transactions with the counterparty to the arrangement (if an entity analogizes to revenue recognition literature for such matters).
- Evaluating whether transactions with the counterparty to the arrangement are viewed as revenue activities (e.g., a biotech company performs contractual research and development (R&D) services for a pharmaceutical company under the arrangement).

This section contains (1) guidance on some of the revenue recognition topics frequently encountered by life sciences entities, (2) a discussion of SEC comment letter themes related to these topics, and (3) a discussion of anticipated changes in the life sciences industry as a result of the new standard on revenue recognition.

Featured Interpretive Guidance

The recognition of product revenue in the pharmaceutical (including biotechnology) industry relies heavily on estimates and assumptions about returns and other potential adjustments to revenue. Restatements and inquiries into the revenue recognition practices in the pharmaceutical industry underscore the need for entities to (1) focus on the criteria for recognizing revenue on the sale of pharmaceutical products and (2) consider various factors in estimating chargebacks, returns, rebates, discounts, promotions, shelf stock adjustments, and other adjustments to revenue.

Chargeback arrangements are common in the pharmaceutical industry. Pharmaceutical companies often sell products to wholesalers (or distributors) under agreements containing various terms under which the products will be managed and sold, including specific pricing and return policies. Under these agreements, wholesalers purchase products from the pharmaceutical companies for resale to retailers (pharmacies, retail stores, or other consumer outlets). Typically, a wholesaler sells a product to a retailer at a price negotiated by the retailer directly with the pharmaceutical company (or predetermined by a governmental program). The retailer then sells the product to the ultimate consumer, who pays for the product directly or provides for payment through some type of insurance program (such as a managed-care or governmental program). The price paid by the retailers to the wholesalers under such negotiated arrangements is often less than the price paid by the wholesalers to the pharmaceutical company. In such instances, the wholesalers will “charge back” to the pharmaceutical company the difference between the wholesalers’ cost and the lower price at which the product was sold to the retailer.

¹ For the full titles of standards and other literature referred to in this publication, see [Appendix A](#). For a list of abbreviations used in this publication, see [Appendix B](#).

Reserves for returns may be more difficult to estimate in the pharmaceutical industry than in many other industries. The pharmaceutical company product sales terms generally include specific return policies (or policies are established through existing practice) that provide the terms under which the product can be returned. The product may be returned to the pharmaceutical company for a variety of reasons. One of the most common reasons is product expiration (which often occurs 18 to 30 months after product manufacturing).

In addition, the agreements usually allow for pricing adjustments in the form of rebates from the pharmaceutical companies to retailers, insurance providers, or governmental agencies (such as Medicaid). These adjustments are based on sales of, or claims paid for, the product.

Distribution arrangements may vary depending on the terms of the agreement with the wholesaler and other terms for the sale of the product. Therefore, the recognition of revenue under these agreements may also vary. Because a number of factors may affect the timing and amount of revenue recognized under these arrangements, it is important for entities to understand the terms under which each product is sold when considering whether revenue is being accounted for appropriately. The discussion below gives an overview of the revenue recognition criteria when a right of return exists, including accounting considerations related to the sale of pharmaceutical products under these types of arrangements.

Revenue Recognition When a Right of Return Exists

As noted above, pharmaceutical companies generally give the buyer the ability to return a product under the terms of the sale agreement. ASC 605 provides guidance on how entities should account for sales of products when the buyer has a return privilege, whether as a matter of contract or in accordance with existing practice. ASC 605-15-25-1 specifies criteria for recognizing revenue when a right of return exists:

If an entity sells its product but gives the buyer the right to return the product, revenue from the sales transaction shall be recognized at time of sale only if all of the following conditions are met:

- a. The seller's price to the buyer is substantially fixed or determinable at the date of sale.
- b. The buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product. . . .
- c. The buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product.
- d. The buyer acquiring the product for resale has economic substance apart from that provided by the seller. . . .
- e. The seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer.
- f. The amount of future returns can be reasonably estimated

Sales revenue and cost of sales that are not recognized at time of sale because the foregoing conditions are not met shall be recognized either when the return privilege has substantially expired or if those conditions subsequently are met, whichever occurs first.

While all of the above criteria must be met for revenue to be recognized, the criteria in ASC 605-15-25-1(a) and ASC 605-15-25-1(f) require entities to use significant judgment in determining when to recognize revenue for products sold under many pharmaceutical arrangements. If a company determines that it cannot reasonably estimate returns, it cannot recognize revenue until the right of return expires or a reasonable estimate of returns can be made. Similarly, if a company determines that the price of the product is not determinable upon shipment to the wholesaler because it cannot estimate chargebacks and rebates, revenue would have to be deferred until the price can be determined. In both instances, such a determination requires careful consideration of all facts and circumstances that affect the sale of the product.

Ability to Reasonably Estimate Returns

Returns in the pharmaceutical industry may occur for a variety of reasons, including product expiry (which can delay the actual return of the product for up to 30 months or more from the date of product manufacturing). Under ASC 605-15-25-1(f), an entity must be able to make a reasonable estimate regarding future returns to recognize revenue upon shipment of

the product (provided that the other requirements of ASC 605 are met). ASC 605-15-25-3 indicates that the ability to make such an estimate depends on many factors and notes that the following factors may impair this ability:

- a. The susceptibility of the product to significant external factors, such as technological obsolescence or changes in demand
- b. Relatively long periods in which a particular product may be returned
- c. Absence of historical experience with similar types of sales of similar products, or inability to apply such experience because of changing circumstances, for example, changes in the selling entity's marketing policies or relationships with its customers
- d. Absence of a large volume of relatively homogeneous transactions.

As noted in ASC 605-15-25-4, while the existence of one or more of the factors listed in ASC 605-15-25-3 may not be sufficient to prevent an entity from making a reasonable estimate, other factors may prevent an entity from doing so. ASC 605-10-S99-1 discusses estimates and changes in estimates and provides the following additional factors to consider that may affect or preclude an entity's ability to make a reasonable and reliable estimate of product returns:

- Significant increases, or excess levels of inventory, in a distribution channel (sometimes referred to as "channel stuffing").
- Lack of "visibility" into, or the inability to determine or observe, the levels of inventory in a distribution channel and the current level of sales to end users.
- Expected introductions of new products that may result in the technological obsolescence, and larger than expected returns, of current products.
- The significance of a particular distributor to the registrant's (or a reporting segment's) business, sales, and marketing.
- The newness of a product.
- The introduction of competitors' products with superior technology or greater expected market acceptance.
- Other factors that affect market demand and changing trends in that demand for the registrant's products.

In addition, the Interpretive Response to Question 4 of SAB Topic 13.A.4(b) discusses the SEC staff's view on how long a history is necessary to estimate returns in a product sale transaction within the scope of ASC 605 and states:

The staff does not believe there is any specific length of time necessary in a product transaction. However, [ASC 605-15] states that returns must be subject to reasonable estimation. Preparers and auditors should be skeptical of estimates of product returns when little history with a particular product line exists, when there is inadequate verifiable evidence of historical experience, or when there are inadequate internal controls that ensure the reliability and timeliness of the reporting of the appropriate historical information. Start-up companies and companies selling new or significantly modified products are frequently unable to develop the requisite historical data on which to base estimates of returns.

While not all the factors in ASC 605 may apply directly to the sale of pharmaceutical products, many of the factors could significantly influence whether the product is ultimately returned. The following factors specific to the pharmaceutical industry could significantly affect the ability to estimate returns:

- Period in which returns can occur.
- Experiences with products (or the inability to apply such experiences to current products).
- Potential channel stuffing.
- Lack of information about product levels and age of product in the distribution channel.
- Predictability of market conditions and competition (e.g., competitive entry of a similar or generic product).
- Current stage in the product life cycle (i.e., initial product launch vs. end/maturity of product life).
- Historical, current, and projected demand.

The period and terms for product returns attributable to expiration may present particular challenges. The terms may specify, for example, that expiration returns may be made no sooner than six months before expiration and no later than 12 months after expiration. Under these common return practices, which may generate most of the returns, an entity may have to use significant judgment and may need significant data to reasonably estimate the returns reserve. Further, a review of subsequent return activity before issuance of the financial statements might be less useful for pharmaceutical companies than it would be for most companies. This is because the expiration returns observed (e.g., in the first two months after year-end) might relate to sales that took place no sooner than 24 months earlier, if we assume a product life of 30 months from the date of sale.

As noted above, fully understanding the terms and conditions under which each product is being sold is key to determining whether revenue is being accounted for appropriately. The mere existence of factors cited in ASC 605 does not necessarily result in the inability to estimate returns. However, while there are no bright lines, sufficient evidence should exist to support the conclusion regarding the impact of each of these factors on the ability to estimate future returns. If there is not sufficient evidence of this ability, revenue should not be recognized until the right of return expires or there is sufficient evidence to estimate future returns.

Further, evaluating these factors for new product launches in the pharmaceutical industry may be even more challenging. The amount of historical information and evidence to support the estimates and assumptions regarding returns could be reduced depending on whether the product is (1) a modification of an existing product, (2) similar to other products in the market, or (3) a completely new product. Obtaining sufficient evidence for new products may be particularly difficult when the company does not have a relevant history for similar products or a clear competitive advantage that allows for more predictable sales. As noted above, the availability of sufficient evidence to support these estimates and assumptions is an important factor in having the ability to recognize revenue.

Ability to Reasonably Estimate Chargebacks and Rebates

In addition to estimating returns, entities must be able to make a reasonable estimate of potential adjustments to the price of the product, such as chargebacks and rebates. Although ASC 605 does not specifically address the accounting for pricing adjustments, ASC 605-15-25-1 requires the seller's price to the buyer to be fixed or determinable for revenue to be recognized. As with the requirement of ASC 605-15-25-1(f), whether the price is determinable depends on the entity's ability to reasonably estimate future adjustments to the amount billed for the product. This ability may be affected by many of the same factors that affect returns. Although ASC 605 does not provide specific factors to consider, the factors used in the evaluation of returns should also be used in the evaluation of whether the price is fixed or determinable, to the extent that those factors are applicable. The following factors may also be helpful in such an evaluation:

- Existence of product-specific historical information regarding chargebacks and rebates.
- Availability and specificity of customer-specific pricing information (including contractual arrangements with retailers, insurance providers, or governmental agencies).
- Information regarding the specific retailer and consumer product sales mix (to understand which customer pricing arrangement is applicable).
- Availability and specificity of customer inventory levels.

As with product returns, the nonexistence of one or more of the above factors, or the existence of one or more of the factors in ASC 605, does not necessarily result in the inability to estimate pricing adjustments. However, sufficient evidence should exist to ensure that the impact of these factors or similar factors does not change the conclusion that the price is fixed or determinable. If sufficient evidence does not exist to support such a conclusion, revenue should not be recognized until the price can be determined.

Thinking It Through

This guidance does not apply to potential adjustments to the price of the product that are based on future performance obligations or other contingencies. Such adjustments may be deemed contingent revenue and are subject to the guidance in ASC 605-15-25-1(e) or other authoritative literature.

Revenue Recognition Q&As

The Q&As below contain guidance on other revenue recognition matters that frequently affect life sciences entities.

Pay-for-Performance Arrangements

Pay for performance in health care gives financial incentives to clinicians for better health outcomes. Clinical outcomes, such as longer survival, can be difficult to measure, so pay-for-performance systems usually measure process outcomes. Also known as “value-based purchasing,” this payment model rewards physicians, hospitals, medical groups, and other health care providers for meeting certain performance measures for quality and efficiency. It penalizes caregivers for poor outcomes, medical errors, or increased costs. For example, if, after a defined treatment period, a patient does not exhibit the predetermined objective criteria, the drug manufacturer could be required to reimburse all or a portion of the amounts originally received upon sale of the drug.

Question

Can a vendor that enters into a pay-for-performance arrangement record revenue at the time of initial sale with a reserve for the portion of sales that it expects will not meet the previously determined criteria, or should revenue be deferred until the close of the refund period?

Answer

Revenue can be recognized at the time of initial sale if the vendor can demonstrate that it has sufficient historical basis to estimate the refunds to which the customer will be entitled. If the vendor does not have a company-specific historical basis to estimate refunds, revenue should be deferred until the close of the predetermined contingency period.

Identifying Deliverables in a Multiple-Element Arrangement

ASC 605-25-15-2 states that the guidance in ASC 605-25 applies to “[a]ll deliverables (that is, products, services, or rights to use assets) within contractually binding arrangements (whether written, oral, or implied . . .).” Further, ASC 605-25-25-4 indicates that a “vendor shall evaluate all deliverables in an arrangement to determine whether they represent separate units of accounting.”

The term “deliverable,” however, is not defined. Accordingly, an entity must use judgment in determining whether an item in a multiple-element arrangement constitutes a deliverable. Throughout an arrangement, a vendor may commit to various “significant” performance obligations (e.g., obligations to provide products, provide services, or grant licenses), each of which may be likely to constitute a deliverable. An entity may also have various “less significant” or “ancillary” performance obligations under the arrangement. In addition, the terms of an arrangement could generally provide the parties with certain protective and other rights, such as a right to participate in a joint governance activity. The entity may need to consider such obligations to determine whether, on the basis of the specific facts and circumstances, they represent deliverables.

Question

What should a vendor consider when determining whether an item in a multiple-element arrangement constitutes a deliverable?

Answer

A vendor should consider the following as it analyzes an arrangement — viewed from the perspective of the customer (i.e., the other party to the arrangement) — to identify potential deliverables:

- Whether an item in the arrangement requires a distinct action from the vendor.
- Whether the exclusion of the item from, or the inclusion of the item in, the arrangement would cause the arrangement fee to vary by more than an insignificant amount.
- Whether the vendor's failure to deliver an item results in (1) the customer's receiving a full or partial refund, (2) the vendor's incurring a contractual penalty, or (3) both.
- Whether all performance obligations (e.g., an obligation to provide a product, service, or right, either at a point in time or over the term of the arrangement) have been identified — particularly performance obligations that (1) may be considered ancillary to the "primary" product(s), service(s), or right(s) being sold or (2) do not have explicit monetary values assigned to them under the terms of the arrangement.
- The degree to which an item is essential to the functionality of other products, services, or rights being sold.
- Whether the customer considers an item significant or of value separately from other deliverables.

This list is not all-inclusive. When identifying deliverables, entities should evaluate the facts and circumstances of each arrangement. Notably, ASC 605-25 does not contain a materiality threshold for identifying deliverables in a multiple-element arrangement.

An example of an ancillary service obligation that could be considered a deliverable (that may or may not have a monetary value assigned to it) is an obligation to participate on a joint steering committee (or committees) throughout the term of the arrangement or without a defined term. Such an obligation is common in collaborative arrangements — particularly in the biotechnology and pharmaceutical industries. However, sometimes an entity may assess the substance and timing of the participation and conclude that such joint steering committee participation does not constitute a deliverable (i.e., the participation represents a right to joint governance for the mutual protection of each party's interest rather than a service obligation). For example, the vendor may have the contractual right to withdraw from, and later rejoin, the joint steering committee without any financial consequences.

Once all deliverables in a multiple-element arrangement have been identified, a vendor should apply the provisions of ASC 605-25-25-5 to determine whether to consider each deliverable a separate unit of accounting.

Example

Company B enters into an arrangement with a customer to deliver highly specialized diagnostic equipment. The arrangement requires that upon installation of the equipment, all testing of the equipment occur at the customer's location. Company B has previously sold the same equipment separately to other customers, and other vendors can perform the installation of the equipment.

When determining what elements of the arrangement constitute deliverables, B would assess the equipment, installation, testing, and other contractual terms of the arrangement. Company B determines that the equipment and the installation are both deliverables because both are sold separately in the marketplace.

Company B would consider the factors above, among others, when determining whether the testing represents a deliverable. If, during the testing of the product, B allowed the customer's employees to consult its installation technicians about key troubleshooting techniques associated with the equipment and the customer acquired knowledge during that process, B may conclude that the testing is a deliverable that it must evaluate under ASC 605-25. That is, B may conclude that the testing is important, has value to the customer, and therefore would cause the arrangement fee to vary by more than an insignificant amount.

Conversely, if the testing of the equipment was a standardized process that is considered perfunctory and results in no transfer of knowledge to the customer, B may conclude that the testing (1) is simply a quality-control function inseparable from the equipment itself and (2) should not be evaluated as a separate deliverable under ASC 605-25.

Contingent Deliverables

Question

Is a contingency in a multiple-element revenue arrangement a deliverable that an entity should evaluate under ASC 605-25?

Answer

A contingency in a revenue arrangement may represent a potential deliverable that may be difficult to analyze under ASC 605-25. The EITF discussed this topic during its deliberations of the guidance (codified by [ASU 2009-13](#)) but ultimately decided not to address contingencies in an arrangement with multiple deliverables, observing that accounting conclusions on this topic are highly dependent on individual facts and circumstances.

The “Issue 08-1 Working Group,” which advised the EITF on this topic, described a contingent deliverable as a revenue-generating activity that is contingent on the occurrence of a future event not exclusively within the control of the customer. If the future event occurs, the vendor is required by the terms of the arrangement to deliver specified products or services. In describing contingent deliverables, the working group noted that such deliverables can be contingent on (1) the actions of a party unrelated to the revenue arrangement (such as a governmental agency), (2) the vendor’s actions, or (3) a combination of both. In some industries and arrangements, contingent deliverables may be prevalent and represent deliverables with considerable value.

The examples below illustrate contingencies that could be considered deliverables under ASC 605-25.

Example 1

Company B is a biotech company that has developed a new technology for monitoring and testing diabetic individuals. Company B grants Customer X a five-year license to its technology. The terms of the license agreement do not require B (i.e., B is not obligated) to perform any additional R&D activities. However, B agrees (i.e., B has a contingent obligation) that if improvements to its technology are made during the next two years, it will provide X with a license to the updated technology on a when-and-if-available basis. Any new license granted to X will terminate at the same time as the original five-year license.

On the basis of all the facts and circumstances, B determines that the obligation to provide a license for improvements to its technology on a when-and-if-available basis represents a deliverable that must be evaluated and accounted for under ASC 605-25.

Example 2

Company C enters into an arrangement in which it agrees (i.e., has an obligation) to provide R&D services to Customer Y on a best-efforts basis for three years. If a commercially viable product is developed as a result of those services, C agrees to manufacture 100 units of the product and deliver them (i.e., has a contingent obligation) to Y. The manufacturing process performed by C is novel since similar manufacturing capabilities are not available in the marketplace. Customer Y agrees to pay C \$1 million for the R&D services.

On the basis of all the facts and circumstances, C determines that the obligation to manufacture and deliver 100 units if a commercially viable product is developed represents a deliverable that must be evaluated and accounted for under ASC 605-25.

Optional Purchases

Question

An optional purchase is a term in an arrangement that gives a customer the option to purchase products or services in the future. Is an optional purchase a deliverable that an entity should evaluate under ASC 605-25?

Answer

It depends. If a revenue-generating arrangement contains an option to buy products or services in the future and the substance of the arrangement is that the customer truly can elect whether to purchase any of those products or services, the option should be evaluated as a separate arrangement and not as a deliverable of the original arrangement. An entity should evaluate the substance of an arrangement in determining whether an optional purchase of future products or services represents a deliverable.

An entity should analyze all relevant facts and circumstances in determining the substance of the arrangement, such as whether the contractual option to purchase the product or service in the future is truly optional to the customer. If, in substance, the option to buy the future product or service is not truly optional because the customer has no choice but to purchase the future product or service, the optional purchase of future products or services would be considered a deliverable of the original arrangement. For example, if an arrangement gave a customer the option to purchase future products or services and those future products and services were necessary for the intended use of the delivered product and not readily obtainable from another party, the optional purchase of future products and services would be considered a deliverable of the original arrangement.

If an arrangement's contractual terms represent options to purchase future products and services in which the quantity ultimately purchased is variable but the customer does not really have the option not to buy the product or service in the future, an entity would conclude that those options represent deliverables of the original arrangement. In addition, if an optional purchase of products or services in the future is considered a deliverable because the future products or services are necessary for the intended use of the delivered product and not readily obtainable from another party, concerns may be raised about whether the delivered item has stand-alone value and whether the arrangement could be separated into multiple units of accounting.

Example

A vendor sells medical equipment to a customer. To function, the medical equipment needs cartridges that are only sold by the vendor. The arrangement gives the customer the option of purchasing these cartridges from the vendor. On the basis of all the facts and circumstances, the vendor determines that the customer's purchase of cartridges in the future is not truly optional because they are required for the intended use of the equipment and are only sold by the vendor. Therefore, the vendor determines that the optional purchase of the cartridges represents a deliverable in the original arrangement that must be evaluated. The vendor should also carefully evaluate whether the medical equipment has stand-alone value given that its functionality depends on the subsequent delivery of the cartridges.

If the optional purchase is not considered a deliverable of the original arrangement, the vendor should still consider whether a discount on optional purchases is present and whether the discount creates a deliverable. In some arrangements, a vendor may provide significant and incremental discounts (i.e., discounts above those that are usually provided in comparable transactions and above any discounts related to other elements in the arrangement) on future purchases of products or services. For guidance on how to account for significant and incremental discounts, see ASC 985-605-55-82 through 55-85 and ASC 985-605-55-185 through 55-200.



Multiple-Element Arrangement Example — Licensing and Supply Arrangement

Company B develops, licenses, manufactures, and sells pharmaceutical products. Company B enters into a separate licensing and supply agreement with an unrelated third-party company (the “distributor”) to sell and market B’s product. The provisions of the licensing agreement are as follows:

- The distributor is responsible for obtaining approval from the relevant regulatory agencies to market and sell B’s product. Proprietary product information required by the regulatory agencies will be provided to the distributor.
- The distributor may not obtain any ownership rights to the proprietary information and is prohibited from selling, subleasing, assigning, or otherwise transferring its rights to the proprietary product information licensed from B.

The separate supply agreement stipulates the following:

- The product will be marketed and sold under the distributor’s name.
- The distributor must purchase all of its supply of the product from B at a specified price index for a minimum of 10 years commencing on the date regulatory approval is obtained.
- The distributor may not manufacture the product in-house.
- The distributor is not permitted to market, sell, or distribute similar products sourced from an alternative supplier.

The licensing agreement requires the distributor to pay B an up-front licensing fee. A portion of this fee (66 percent) is refundable if the distributor is unable to receive regulatory approval to sell and market B’s product. Payments for the product are due as the distributor purchases its supply for resale from B.

Question

Should the separate deliverables — the license and product — be accounted for as separate units of accounting?

Answer

No. The license has no stand-alone value since the distributor has no ability to resell it and is not allowed to use it to manufacture or source the product from anyone but B. Accordingly, the license and product should be accounted for as one combined deliverable for revenue recognition purposes, in accordance with ASC 605-25-25-5 and 25-6, which state the following:

In an arrangement with multiple deliverables, the delivered item or items shall be considered a separate unit of accounting if both of the following criteria are met:

- a. The delivered item or items have value to the customer on a standalone basis. The item or items have value on a standalone basis if they are sold separately by any vendor or the customer could resell the delivered item(s) on a standalone basis. In the context of a customer’s ability to resell the delivered item(s), this criterion does not require the existence of an observable market for the deliverable(s).
- b. Subparagraph superseded by [ASU] 2009-13.^[2]
- c. If the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item or items is considered probable and substantially in the control of the vendor. . . .

A delivered item or items that do not qualify as a separate unit of accounting within the arrangement **shall be combined** with [the amount allocable to] the other applicable undelivered item(s) within the arrangement. **The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting.** [Emphasis added]

² ASU 2009-13 eliminated the criterion formerly in ASC 605-25-25-5(b) that stated, “There is objective and reliable evidence of fair value of the undelivered item(s).”

Medical Device Excise Tax

As a result of the Patient Protection and Affordable Care Act of 2010, Section 4191 of the Internal Revenue Code imposes a 2.3 percent excise tax on sales of certain medical devices by manufacturers, producers, or importers of the devices. This tax is referred to as the medical device excise tax (MDET). The MDET has been in effect since 2013, but the Protecting Americans From Tax Hikes Act of 2015, which was signed into law in December 2015, includes a two-year suspension of the tax, which applies to sales on or after January 1, 2016, and before January 1, 2018.

Question

Is the MDET within the scope of ASC 605-45?

Answer

Whether the MDET is within the scope of ASC 605-45 depends on how it is incurred. Because the MDET is imposed on the basis of an individual legal entity, the tax can be triggered by both third-party and intercompany sales. Therefore, in evaluating the applicability of ASC 605-45, an entity will need to determine whether the tax is imposed on a sale to a customer (a third-party sale) or before a sale to a customer (an intercompany sale):

- *Third-party sales* — When the MDET is imposed on a third-party sale, it would be within the scope of ASC 605-45. Accordingly, an entity may elect (or may have already elected) as an accounting policy to present the tax “on either a gross basis (included in revenues and costs) or a net basis (excluded from revenues)” in accordance with ASC 605-45-50-3.
- *Intercompany sales* — When the MDET is imposed on an intercompany sale, it would be outside the scope of ASC 605-45 because the tax is not assessed “on and concurrent with a specific revenue-producing transaction between a seller and a customer” in accordance with ASC 605-45-15-2(e). In such circumstances, some entities may view the MDET as a cost of preparing the medical device for sale, in which case capitalization of the MDET into inventory may be permitted (until a third-party sale occurs) under ASC 330.

As entities evaluate their accounting for the MDET, they should determine whether they have an existing policy for excise taxes with characteristics similar to those of the MDET and, if so, should consider whether to apply this policy to their accounting for the MDET.

Medicare Coverage Gap Discounts

As a result of the Patient Protection and Affordable Care Act, entities participating in Medicare Part D must provide Medicare beneficiaries in the Medicare coverage gap (or “donut hole”) with a 50 percent discount in their Medicare prescription drug coverage.

Question

How should an entity recognize discounts related to the Medicare coverage gap?

Answer

No accounting literature directly addresses the accounting for discounts offered to individuals in the Medicare coverage gap. However, we believe that there are two acceptable models for such accounting:

- An entity may apply the “specific identification” (or “point-of-sale”) model by estimating which sales of prescription drugs are to individuals expected to be in the Medicare coverage gap and recognizing the respective discount as a reduction of revenue for those sales. Under this model, the discount provided to the individual in the Medicare coverage gap is attributed to the specific party (i.e., the particular Medicare beneficiary) that would have been considered the payer. Accordingly, the discount is recognized similarly to how the entity recognizes other discounts or pricing adjustments that would be attributed to other payers. In applying this method, the entity must estimate

when the coverage gap payment would be triggered on the basis of its product portfolio and sales volumes and record that estimate in the initial quarter that is affected.

- An entity may apply a “spread” (or “effective rate”) model in which it estimates the total discount to be provided to individuals in the Medicare coverage gap for the annual period and uses a systematic and rational allocation method to recognize that discount as a reduction of revenue for sales that are attributed to Medicare beneficiaries (e.g., ratably as a percentage of all sales to Medicare beneficiaries during the year). The discount provided while the individual is in the Medicare coverage gap is considered similar to a contingent sales incentive, as discussed in ASC 605-50, on the basis that the discount agreement is a condition of participating in Medicare Part D and that such discounts are attributable to all respective Medicare revenues for the year. Under this method, entities could potentially record the impact before the quarterly period in which the gap coverage is actually triggered. In addition, the impact could go beyond the upper limit of the coverage gap because the entity is applying a ratable approach.

An entity should use either the specific identification model or the spread model for the discounts associated with sales attributed to the Medicare coverage gap and should apply the method consistently.

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.

Question

What considerations pertain to the accounting for a collaborative arrangement?

Answer

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 the 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 808-10-20 defines a collaborative arrangement as a contractual arrangement that involves a joint operating activity and 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:

- a. Directing and carrying out the activities of the joint operating activity
- b. Participating on a steering committee or other oversight or governance mechanism
- c. 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:

- a. Services are performed in exchange for fees paid at market rates.
- b. A participant is able to exit the arrangement without cause and recover all (or a significant portion) of its cumulative economic participation to date.
- c. Initial profits are allocated to only one participant.
- d. 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) the "stage of the endeavor's life cycle" and (2) the "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, entities 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 collaborative arrangement for which a biotech company and pharmaceutical company agree to coproduce and commercialize a newly approved drug, the biotech company may also agree to provide the pharmaceutical company with R&D services that represent the biotech company's ongoing major or central operations. In such cases, the biotech 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 collaborative arrangement.

In the accounting for payments between counterparties in a collaboration arrangement, questions have arisen regarding whether the presence of loss-sharing provisions during commercialization could affect whether any consideration received, including up-front payments deemed "nonrefundable," would not be considered fixed or determinable (and therefore would be treated as either a liability or deferred revenue depending on the facts and circumstances). Arrangement consideration may not be fixed or determinable if an entity concludes that the loss-sharing provision requires the recipient to effectively refund all or a portion of the consideration received when (1) the collaboration incurs losses in commercialization and (2) loss-sharing payments are required to be made to the party that paid the consideration. We believe that in assessing whether consideration received is fixed or determinable, an entity should consider, among other factors, the stage of

the endeavor and the likelihood of the future loss-sharing payments under the arrangement. For example, an entity may determine that an up-front payment received at the outset of an R&D and commercialization arrangement is fixed and determinable if (1) there is significant uncertainty that commercialization is unlikely at the outset of the agreement given the early stage of development of the compound (and, therefore, the loss-sharing provision would never apply) or (2) commercialization is expected to be profitable. However, if consideration (i.e., an up-front payment) is received in connection with an arrangement entered into at or near the time of regulatory approval of a drug whose commercialization is expected to result in losses, and the arrangement requires the party receiving the up-front payment to share in losses, such party is effectively refunding the up-front consideration and would generally conclude that the consideration is not fixed or determinable regardless of whether the consideration, in form, is referred to in the arrangement as nonrefundable.

When determining the appropriate income statement presentation of amounts recorded as a result of a collaborative arrangement, entities also will need to separately evaluate (1) transactions with third parties outside of the arrangement and (2) transactions between collaboration participants. ASC 808 requires that each collaboration participant report costs incurred and revenue generated from transactions with third parties in its income statement in accordance with the principal-versus-agent guidance in ASC 605-45. The participant in the collaborative 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 on the basis of 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.

We believe that when an entity makes an analogy to authoritative accounting literature, all (as opposed to limited) aspects of that literature should be applied to the extent applicable. For example, a biotech company may enter into a collaboration arrangement with a pharmaceutical company and, as part of the collaboration, (1) provide the pharmaceutical company a license to use intellectual property related to a drug candidate and (2) perform R&D services jointly with the pharmaceutical company. The biotech company may conclude that the revenue literature is applicable by analogy for determining the unit(s) of accounting, recognition, and measurement. Accordingly, if the biotech company concludes that the license does not have stand-alone value apart from the R&D services to be performed, the revenue literature would require the license and R&D services to be combined for accounting purposes. Further, with respect to the appropriate income statement presentation for consideration allocated to the combined unit of accounting (in this case, the license and R&D services), such consideration would generally be presented consistently in the same category for income statement presentation purposes given the conclusion that the license and R&D services should be combined for accounting purposes.

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 property 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.

Question

What considerations pertain to the accounting for R&D funding arrangements?

Answer

To determine the appropriate accounting treatment, life sciences companies should consider, among other things, the risks associated with the R&D program being funded, as well as the deliverable(s) to be provided to the funding party. If a life sciences entity receives funding after it has already determined that successful completion of the R&D is probable (i.e., the transfer of financial risk involved with R&D from the life sciences entity to the funding party is not substantive and genuine), it may be more appropriate to treat the arrangement as the sale of future revenues in accordance with ASC 470-10-25 than as an R&D funding arrangement in accordance with ASC 730-20. It is also important to understand to what extent revenue deliverables are present in the arrangement (i.e., license rights to intellectual property subject to the R&D program) since this may inform the accounting literature to consider, particularly if a conclusion is reached that the arrangement is a contract to perform services that should be accounted for in accordance with ASC 605. Assuming that the risk of R&D is substantive and genuine, however, 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 provision lists the following examples of circumstances in which risk has not been transferred:

- a. 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.
- b. The other parties can require the entity to purchase their interest in the research and development regardless of the outcome.
- c. 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:

- a. 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.
- b. 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. . . .
- c. 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.
- d. The entity has essentially completed the project before entering into the arrangement.

Thinking It Through

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 ASC 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.

Thinking It Through

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. Such evaluation is critical 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.

R&D Legal Entities

Question

What considerations should be taken into account when an R&D arrangement involves the formation of a new legal entity?

Answer

Historically, it was not common for separate legal entities to be created to facilitate R&D funding arrangements; however, many recent arrangements have included the formation of a new legal entity. Typically, the new legal entity is 100 percent owned by a financial investor, and the pharmaceutical company may be involved through participation on a committee

(e.g., steering committee) or by performing R&D services through an outsourcing arrangement. The pharmaceutical company may also have the right or option to reacquire the rights to the compound(s) at a later date.

When an R&D arrangement involves the formation of a new legal entity, consideration must also be given to the consolidation guidance in ASC 810 to determine whether the pharmaceutical company is required to consolidate the legal entity. Typically, the R&D legal entity is a variable interest entity because (1) the power to direct the activities of the legal entity is not possessed by the equity investors or (2) the pharmaceutical company's right or option to reacquire the rights to the compound effectively limits the returns that can be received by the financial investor. In these situations, the evaluation should include consideration of whether the pharmaceutical company has the power to direct the activities most significant to the legal entity's economic performance. For example, the power to make decisions related to the design or operation of clinical studies may indicate that the pharmaceutical company has power over the entity's most significant activities and that therefore, consolidation may be required. The power to make the most significant decisions could reside with different parties depending on a product candidate's stage of development and should be considered in the consolidation analysis. Further, careful consideration should also be given when the decisions of the financial investor(s) are passive or predetermined, or when the pharmaceutical company has a fixed-price call option to acquire the legal entity, since these types of circumstances could suggest that (1) the financial investors lack the characteristics of a controlling financial interest and (2) the pharmaceutical company controls and should consolidate the legal entity.

If a pharmaceutical company concludes that consolidation of an R&D entity is required, the percentage of equity not owned by the pharmaceutical company would be presented as a noncontrolling interest (which could be 100 percent of the legal entity's equity). Further, it is important to determine whether the financial investor's equity investment has all of the characteristics of equity. If it does not, temporary equity or liability classification of the noncontrolling interest may be required depending on the facts and circumstances.

SEC Comment Letter Themes

Collaborative Arrangements

Examples of SEC Comments

- In order to help us understand more fully how your collaborative arrangements impact your financial statements for each period presented, please provide us, in table format, the amounts . . . by year and by line item included in your statements of operations attributable to transactions arising from collaborative arrangements between you and the other participants and third-parties. Please provide separate tables for each of your "significant" collaborative arrangements and for all of your collaborative arrangements in the aggregate (i.e. the "significant" arrangements and all other arrangements). Present separately amounts with other participants and third-parties that are netted in a financial statement line item.
- You indicate that collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. Tell us your accounting policies regarding separation and allocation for your collaborative arrangements.
- Although you disclose your accounting policies for income you generate as a result of collaboration agreements under "revenue recognition" . . . , tell us your accounting recognition for other aspects of these arrangements and where these policies are disclosed.

Collaborative arrangements are common among biotech and pharmaceutical companies. 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 in the industry about the nature of, and

accounting for, their collaborative arrangements and has continued to probe them to better understand the basis for such accounting under U.S. GAAP.

Inquiries to registrants have focused on the registrant's conclusion about whether certain transactions with the collaboration partner represent true vendor-customer activities. Collaborative arrangements within the scope of ASC 808 are based on the premise that each party to the agreement assumes a proportionate share of risks and, therefore, a vendor-customer relationship does not exist. Even if the registrant concludes that it is a party to a collaborative agreement, however, there may be circumstances in which certain elements of the agreement represent activities that are similar to those in a vendor-customer relationship. Accordingly, the SEC staff seeks to understand the registrant's accounting policies regarding separation (i.e., unit of accounting) and allocation (i.e., when multiple units exist) for collaborative arrangements.

In addition, since collaborative arrangements often include up-front payments, royalty or profit-share payments, and expense reimbursements, the SEC staff has requested supplemental explanation of the registrant's determination and disclosure of (1) the separation, allocation, recognition, and classification principles that were used to account for payments between collaboration partners and (2) the factors that led the registrant to conclude that it is the principal (or agent) in transactions with third parties.

The SEC staff also has requested enhanced disclosures about registrants' collaborative agreements, including the overall effect of collaborative arrangements on the financial statements. SEC staff requests for such disclosures have focused on clearly describing the material terms of a collaborative arrangement, 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. Further, the SEC staff has asked that registrants prepare a tabular summary to provide it with a composite disclosure of the financial statement impact of all collaborative arrangements. For all periods presented, the SEC staff may request a separate table for each significant collaborative arrangement and a table for all collaborative arrangements in the aggregate; in addition, the SEC staff may request separate presentation in such tables of amounts attributable to transactions with other participants and third parties that are presented net in a financial statement line item.

Further, the SEC staff may ask registrants to file a material collaborative arrangement as an exhibit to their filing in accordance with SEC Regulation S-K, Item 601(b)(10). For more discussion, see the Material Contracts section of Deloitte's *SEC Comment Letters — Including Industry Insights: What "Edgar" Told Us* (updated October 2015).

Milestones

Example of an SEC Comment

Your disclosure . . . lists the awarding of a license as an example of an appropriate milestone for revenue recognition. Please provide us with a detailed explanation of your basis for previously recognizing this revenue, including the specific milestones previously reached that made recognition of the revenue on the affected contracts appropriate. Also, please clarify your ongoing revenue recognition policy in terms of when it is appropriate to recognize revenue prior to obtain[ing] a license.

The SEC staff has continued to comment on disclosures related to the milestone method of revenue recognition under ASC 605-28. When such disclosures apply, the SEC staff will review the registrant's 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.

Registrants in the industry will often make adjustments for milestones when determining non-GAAP income. For a discussion of adjustments made by registrants when determining their non-GAAP measures, see the Non-GAAP Financial Measures and Key Metrics section of Deloitte's *SEC Comment Letters — Including Industry Insights: What "Edgar" Told Us*.

Multiple-Element Arrangements

Examples of SEC Comments

- You disclose that you recognize revenue from the licensing of product rights and the performance of research or selling activities over the periods earned. Please tell us the amounts of each of these streams of [revenue] you recognized in each of the last three years and address the following:
 - Tell us your consideration for disclosing each revenue stream separately under Item 5-03.1 of Regulation S-X;
 - Tell us your consideration for disclosing the terms of any material arrangements under which these revenues are earned; and
 - To the extent these streams are material, provide us proposed revised policy disclosure to be provided in future periodic reports that clarifies how you recognize these revenues "over the periods earned."
- Please provide us a) a description of each component included in and b) a full analysis of your accounting treatment of your . . . termination of the alliance agreements and sale of [a] business. Include reference to authoritative literature supporting your separation, allocation, recognition and classification of the various components. Also provide in your response your supporting computations including those supporting the composition and allocation of the \$[X] consideration and the gain on sale of \$[X].

The SEC staff often asks registrants in the life sciences industry to expand or clarify their disclosures about multiple-element arrangements, particularly those involving licenses of product rights and other deliverables. 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 the description is complete (i.e., that all material terms are disclosed for each revenue stream), and (3) precisely describing the rights conveyed by the license.

In addition, the SEC staff has 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 SEC staff has 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). For more information about multiple-element arrangements and other revenue-related considerations, see the Revenue Recognition section of Deloitte's *SEC Comment Letters — Including Industry Insights: What "Edgar" Told Us*.

On the Horizon

Background

On May 28, 2014, the FASB and IASB issued their final standard on revenue from contracts with customers. The standard, issued as [ASU 2014-09](#) by the FASB and as [IFRS 15](#) by the IASB, outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The FASB and IASB subsequently issued [ASU 2015-14](#) and [Effective Date of IFRS 15](#), respectively, which defer the effective date of the new revenue standard for all entities. ASU 2015-14 provides that for public business entities (as well as certain not-for-profit entities and employee benefit plans) and nonpublic entities, the standard will be effective for annual periods beginning after December 15, 2017, and December 15, 2018, respectively, with certain early adoption provisions available.

In addition, the FASB and transition resource group (TRG) on revenue recognition continue to deliberate various aspects of the standard that will have implications on how life sciences companies account for revenue transactions; refer to [Implementation Developments and Considerations](#) below for further discussion.

ASU 2014-09 states that the core principle of the new revenue recognition guidance is that 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.” The ASU indicates that an entity should perform the following five steps in recognizing revenue:

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

As a result of the ASU, entities will need to comprehensively reassess their current revenue accounting policies and determine whether changes are necessary. In addition, the ASU requires significantly expanded disclosures about revenue recognition, including 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 new revenue standard; and (3) the assets recognized from costs to obtain or fulfill a contract with a customer.

For more information about the revenue ASU, see Deloitte’s [Revenue From Contracts With Customers: A Roadmap to Applying the Guidance in ASU 2014-09](#), its June 2014 [Life Sciences Spotlight](#), and its [TRG Snapshot](#) series.

Key Accounting Considerations

Identifying the Performance Obligations in the Contract (Step 2)

The ASU’s guidance on determining whether a customer can benefit from a good or service on its own, or with other readily available resources, is generally consistent with the current guidance in ASC 605-25 on determining whether a good or service has stand-alone value. However, the requirement that a good or service be “separately identifiable from other promises in the contract” is a new concept under which entities must further evaluate a good or service for separability. For example, life sciences entities that sell a license bundled with contract research services may need to use significant judgment when determining whether the goods or services in a contract are “highly dependent on, or highly interrelated with” or “significantly modify or customize” each other. This new concept may require entities to account for a bundle of goods or services, which may represent a separate unit of accounting under current U.S. GAAP, as a single performance obligation (unit of accounting).

Life sciences entities may also need to use significant judgment in evaluating whether options, in the context of license arrangements in the industry, convey a material right to a customer. Options that are deemed to represent material rights — and, therefore, a performance obligation — would result in a deferral of revenue associated with that performance obligation.

Determining the Transaction Price (Step 3)

The ASU’s less restrictive guidance on variable consideration will most likely result in earlier recognition of revenue under the ASU than under current U.S. GAAP. The following are some specific instances in which revenue may be recognized earlier:

- *Milestones* — An entity may determine that the constraint has been satisfied before the milestone is achieved (i.e., the current recognition requirement under ASC 605-28). However, in such instances, the actual recognition of the consideration included in the transaction price would still depend on the treatment of the milestone under

the remaining steps of the model. First, an entity must determine whether a milestone payment is associated with a separate performance obligation or the contract as a whole (i.e., all the performance obligations) and allocate the associated consideration in such a manner. Then, under step 5 of the revenue recognition model, the actual recognition of the consideration included in the transaction price would depend on whether and, if so, how the underlying performance obligation is satisfied.

- *Product sales currently accounted for under the sell-through method* — An entity may conclude that there is a basis on which to recognize some amount of revenue in circumstances in which it would currently be deferred (e.g., because of the inability to reasonably estimate returns under ASC 605-15 or the lack of a determinable sales price under SAB Topic 13); thus, revenue recognition in such situations may no longer be an “all or nothing” proposition. However, in such instances, the actual recognition of the consideration included in the transaction price would still primarily depend on whether the underlying performance obligation is satisfied (i.e., a transfer-of-control assessment under step 5).
- *Sales of intellectual property* — An entity eligible to receive a future stream of payments in connection with the sale of intellectual property would need to assess whether the threshold for inclusion in the transaction price has been satisfied, both at inception and throughout the arrangement. For example, an entity may determine that there is a minimum amount of future royalties to be collected under the arrangement and that the reversal of this amount is not probable if it were to be recognized up front. Royalties related to the license of intellectual property, however, are subject to a different constraint, described in the [Licenses](#) section below. Therefore, distinguishing between the sale and license of intellectual property will be critical to determining when sales- or usage-based payments are included in the transaction price.

To comply with the ASU’s requirements for estimating the transaction price and determining what amount, if any, is subject to potential reversal (and should be excluded from the transaction price), management will (for some arrangements in the life sciences industry) need to use significant judgment, particularly since the transaction price must be updated in each reporting period. Further, for each arrangement, management will need to consider which measurement approach (i.e., expected value vs. most likely amount) is more predictive.

In addition, for life sciences entities, a significant financing component may exist in arrangements involving the license or sale of intellectual property because of variations in the timing of payments versus the satisfaction of the performance obligation. For example, a financing component could exist when a significant up-front fee is received in connection with the license of intellectual property for which revenue is being recognized over time. However, the ASU also indicates that when a “substantial amount” of consideration is variable and not “substantially within the control” of either party to the contract, a contract would not have a significant financing component. Therefore, if such a license arrangement also requires the payment of sales-based royalties (that are viewed as a substantial portion of the total consideration), a significant financing component would not be present under the ASU. Management may need to use significant judgment in applying the notions of “substantial amount” and “substantially within the control.”

Recognize Revenue When (or as) the Entity Satisfies a Performance Obligation (Step 5)

Life sciences entities may enter into arrangements, such as contract research, that are accounted for under the proportional performance method. Under ASU 2014-09, an entity cannot automatically use similar accounting to recognize revenue; instead, one of three criteria must be satisfied for revenue to be recognized over time:

- a. The customer simultaneously receives and consumes the benefits provided by the entity’s performance as the entity performs
- b. The entity’s performance creates or enhances an asset . . . that the customer controls as the asset is created or enhanced
- c. The entity’s performance does not create an asset with an alternative use to the entity . . . and the entity has an enforceable right to payment for performance completed to date.

Arrangements that fail to meet any of these criteria would be recognized at a point in time, similarly to how they are recognized under the completed-contract method in current practice.

In addition, the ASU requires entities to recognize revenue by using a control-based model rather than the risks-and-rewards model under current U.S. GAAP. While this requirement will generally not affect the timing of revenue recognition in the life sciences industry, exceptions may exist.

Further, life sciences entities will need to carefully review contract terms and practices related to product returns. In doing so, an entity would first evaluate whether control of the product has been transferred to the customer and would then consider the requirements for assessing variable consideration.

Licenses

The license constraint will generally result in the recognition of sales-based royalties and payments in a manner consistent with current practice. However, an exception related to minimum royalties may arise. Specifically, an entity may conclude that a portion of the consideration under the arrangement, because of its fixed nature (e.g., a guaranteed minimum), does not constitute a sales- or usage-based royalty and therefore may be included in the transaction price at the inception of the arrangement and recognized as revenue up front (if the license represents a performance obligation satisfied at a point in time for which a transfer of control has occurred). However, the actual recognition of the consideration included in the transaction price would still depend on whether and, if so, how the underlying performance obligation is satisfied.

To determine whether a license is transferred to a customer at a point in time (right of use) or over time (right to access), life sciences entities must first determine whether a license is distinct (under step 2) before considering the above criteria. If a license is not distinct (i.e., it is combined with other goods or services into a performance obligation), entities would use the general criteria for assessing whether a performance obligation is satisfied over time.

Even when licenses in the industry qualify for revenue recognition at a point in time, the variable consideration constraint — and, more specifically, the exemption from including sales-based royalties and payments in the transaction price — may still result in the recognition of revenue over time. For example, if a license represents a performance obligation satisfied at a point in time (i.e., at inception) but payments under the license are sales-based royalties, revenue would still be recognized over time (i.e., as the royalty payments are triggered).

Collaborative Arrangements

The ASU broadly applies to contracts with customers and 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 in exchange for consideration.” The ASU notes that a counterparty would not be a customer if “the counterparty has contracted with the entity to participate in an activity or process in which the parties to the contract share in the risks and benefits that result from the activity or process (such as developing an asset in a collaboration arrangement) rather than to obtain the output of the entity’s ordinary activities.”

The ASU does not change the guidance in ASC 808-10 on the income statement presentation and classification, and disclosures, applicable to collaborative arrangements within the ASU’s scope. While entities will need to evaluate whether the counterparty to a collaborative arrangement meets the ASU’s definition of a customer, the activities currently accounted for under ASC 808-10 are generally not likely to be within the scope of the ASU since ASC 808-10 currently requires that entities share in “significant risks and rewards.” However, the extent to which the ASU would be applied, by analogy, to activities in a collaborative arrangement remains to be seen.

Contract Costs

The ASU contains criteria for determining when to capitalize costs associated with obtaining and fulfilling a contract. Specifically, entities are required to recognize an asset for incremental costs of obtaining a contract (e.g., sales commissions) when those costs are expected to be recovered (as a practical expedient, a recognized asset with an amortization period of less than a year can be expensed as incurred). Costs of fulfilling a contract (that are not within the scope of other standards) would be capitalized only when they (1) are directly related to a contract, (2) generate or enhance resources that will be

used to satisfy performance obligations, and (3) are expected to be recovered. Capitalized costs would be amortized in a manner consistent with the pattern of transfer of the goods or services to which the asset is related (which may extend beyond the original contract term in certain circumstances).

Life sciences entities may need to consider the impact of the ASU's guidance on their current cost capitalization practices, if any. Some contracts in the industry may not qualify for the practical expedient (i.e., exemption from capitalization) because of their duration. As a result, some life sciences entities may be required to capitalize qualifying costs and thus may need to use judgment in determining (1) which acquisition costs are incremental to a contract with a customer (e.g., questions may arise regarding complex commission structures), (2) the period over which capitalized costs will be amortized (i.e., the amortization period could extend beyond the initial contractual period if the customer relationship is expected to be longer), and (3) the approach to monitoring the resulting assets for impairment on an ongoing basis (this may be challenging when there is a large volume of underlying contracts).

Collectibility

The ASU's collectibility threshold is similar to that in SAB Topic 13. However, arrangements in the life sciences industry may contain significant amounts of variable consideration (e.g., discounts, concessions). Under the ASU, entities will be required at contract inception to assess whether it is probable that they will collect the consideration to which they expect to be entitled in exchange for goods or services that will be transferred to a customer.

Leases

The ASU does not apply to certain contracts with customers that are within the scope of other applicable guidance, such as the leases guidance in ASC 840. In addition, certain elements of arrangements within the scope of the ASU may still be outside the ASU's scope, in which case the consideration allocated to such elements would generally be based on the other standard's allocation requirements. For example, a medical device company that leases equipment with the sale of consumables or services is currently required to separate the equipment lease from the other elements of the arrangement. Under ASC 842-10-15-28, after concluding that a contract contains a lease in accordance with ASC 842-10-15-2 through 15-27, an entity is required to identify any separate lease components in the contract as well as nonlease components. However, the new leases standard, [ASU 2016-02](#), provides a practical expedient in ASC 842-10-15-37 under which "a lessee may, as an accounting policy election by class of underlying asset, choose not to separate nonlease components from lease components and instead to account for each separate lease component and the nonlease components associated with that lease component as a single lease component."



Implementation Developments and Considerations

TRG Discussions

Upon issuing ASU 2014-09 and IFRS 15, respectively, the FASB and IASB formed their joint TRG on revenue recognition. Comprising both FASB and IASB constituents, the group is intended to help the boards identify and consider any diversity in practice related to application of the new revenue standard and address implementation issues as they arise. Accordingly, the TRG does not issue guidance but discusses issues in public. It is anticipated that additional revenue guidance may be issued by the boards as a result of the TRG's discussions. For information on discussions held at the TRG meetings, refer to Section 18 of Deloitte's *Revenue From Contracts With Customers: A Roadmap to Applying the Guidance in ASU 2014-09* and Deloitte's *TRG Snapshot* series.

The TRG has held six meetings since it was formed. These meetings have resulted in the one-year deferral of the standard's effective date, as described above, and certain other proposed clarifications to the new guidance.

Board Deliberations and Proposed ASUs

Below are key takeaways from FASB and IASB deliberations and proposed ASUs that may affect life sciences companies.

FASB-IASB Joint Meeting (February 2015)

At their February 18, 2015, joint meeting, the FASB and IASB tentatively decided to clarify certain aspects of their new revenue standard related to licenses of intellectual property and identifying performance obligations. For more information, including a table summarizing and comparing the boards' tentative decisions, see Deloitte's February 19, 2015, [Heads Up](#).

Proposed ASU on Identifying Performance Obligations and Licensing

On May 12, 2015, the FASB issued a [proposed ASU](#) that would amend the guidance on identifying performance obligations and the implementation guidance on licensing. The proposed amendments include the following:

- Identifying performance obligations:
 - *Immaterial promised goods or services* — Entities would be allowed to disregard goods or services promised to a customer that are immaterial within the context of the contract.
 - *Shipping and handling activities* — A practical expedient would be added to allow shipping or handling activities occurring after control has passed to the customer to be treated as a fulfillment cost rather than a revenue element (i.e., a promised service in the contract).
 - *Identifying when promises represent performance obligations* — The proposal would refine the separation criteria for assessing whether promised goods or services are distinct — specifically, the “separately identifiable” principle (the “distinct within the context of the contract” criterion) and supporting factors.
- Licensing implementation guidance:
 - *Determining the nature of an entity's promise in granting a license* — Intellectual property would be classified as either functional or symbolic, and such classification would generally dictate whether, for a license granted to that intellectual property, revenue must be recognized at a point in time or over time, respectively.
 - *Sales-based and usage-based royalties* — The sales-based and usage-based royalty exception would apply whenever the royalty is predominantly related to a license of intellectual property. The proposed ASU therefore indicates that an “entity would not split a sales-based or usage-based royalty into a portion subject to the guidance on sales-based and usage-based royalties and a portion that is not subject to that guidance.”

For more information, see Deloitte's May 13, 2015, [Heads Up](#).

Proposed ASU on Principal-Versus-Agent Considerations

On August 31, 2015, the FASB issued a [proposed ASU](#) that would amend the new revenue standard to address issues raised regarding how an entity should assess whether it is the principal or the agent in contracts that include three or more parties. In particular, stakeholders have questioned (1) how to determine the unit of account (i.e., whether it should be at the contract level or the performance-obligation level), (2) whether the related indicators in the new revenue standard are intended to assist in a single evaluation of control or represent an additional evaluation, and (3) how certain indicators are related to the new revenue standard's general control principle.

The proposed ASU would clarify that an entity should evaluate whether it is the principal or the agent for each specified good or service (i.e., each good or service or bundle of distinct goods or services that is distinct) promised in a contract with a customer. In addition, the proposal would add guidance to help entities determine the nature of promises in a contract and the types of goods or services that the principal may control. The proposed ASU would also reframe the indicators in the new revenue standard to illustrate when an entity may be acting as a principal instead of when an entity acts as an agent. The proposed ASU would not give any indicator more weight than others in the assessment.

For more information, see Deloitte's September 1, 2015, [Heads Up](#).

Proposed ASU on Narrow-Scope Amendments and Practical Expedients

On September 30, 2015, the FASB issued a [proposed ASU](#) that would amend certain aspects of the new revenue standard. The proposed amendments, which would clarify, rather than change, the new revenue standard's core revenue recognition principle, include the following:

- *Collectibility* — The assessment of collectibility would be clarified with respect to determining when an entity would recognize as revenue consideration it receives if the entity concludes that collectibility is not probable.
- *Presentation of sales tax and other similar taxes collected from customers* — Entities would be permitted to present revenue net of sales taxes collected on behalf of governmental authorities (i.e., to exclude sales taxes that meet certain criteria from the transaction price).
- *Noncash consideration* — In determining the transaction price for contracts containing noncash consideration, an entity would include the fair value of the noncash consideration to be received as of the contract inception date. Further, subsequent changes in the fair value of the noncash consideration after contract inception would be subject to the variable consideration constraint only if the fair value varies for reasons other than the form of the consideration.
- *Contract modifications and completed contracts at transition* — The proposal would add a practical expedient for contract modifications at transition and would define completed contracts as those for which all (or substantially all) revenue was recognized under the applicable revenue guidance before the new revenue standard was initially applied.
- *Transition technical correction* — Entities that elect to use the full retrospective transition method to adopt the new revenue standard would no longer be required to disclose the effect of the change in accounting principle on the period of adoption (as is currently required by ASC 250-10-50-1(b)(2)); however, entities would still be required to disclose the effects on preadoption periods that were retrospectively adjusted.

For more information, see Deloitte's October 2, 2015, [Heads Up](#).

Other Considerations

See Deloitte's January 14, 2016, [Heads Up](#) for additional considerations related to implementing the new revenue standard, including data from an informal Deloitte-sponsored survey.



Acquisitions and Disposals

Introduction

Worldwide, the growing demand for health care services, fueled by aging populations and burgeoning middle classes — along with expectations of higher-quality care and a squeeze on funding — is driving a need for new business models. With public finances stretched and austerity measures in place in the aftermath of the global financial crisis, governments in countries from the United States and the United Kingdom to Japan, China, and Brazil are rethinking their health care strategies. In such an environment, companies must find new ways to improve the efficiency of their operations, increase their R&D capabilities, tap into alternative sources of innovation, and acquire new customers. As a result of these challenges, significant mergers and acquisitions (M&A) activity has occurred in the life sciences industry in recent years. Manufacturers have continued to search for opportunities to access new markets, mitigate risk, and replace revenues and cash flows lost because of pricing pressures and patent expirations associated with the “patent cliff.”

An entity must use significant judgment in applying the guidance on accounting for M&A transactions. For example, the application of the guidance in ASC 805 on accounting for business combinations can differ significantly depending on whether the acquired entity is considered a “business” or an “asset.” Similarly, application of the guidance in ASC 205 on the presentation and disclosure of discontinued operations related to divestiture transactions fundamentally affects financial statement presentation.

This section provides guidance on some of the accounting issues related to acquisitions and divestitures that life sciences entities frequently encounter, including a discussion of recent SEC comment letter feedback on this topic and an update on relevant FASB standard setting.

Featured Interpretive Guidance

The Q&As below contain guidance on acquisition and disposal topics that frequently affect life sciences entities.

Acquisitions

Determining Whether an Asset Group Constitutes a Business

In recent years, M&A activity has increased in the life sciences industry as entities have continued to look for ways to expand their pipeline of products in development. An entity must use significant judgment in evaluating whether a transaction represents the acquisition of a business.

Question

What asset groups constitute a business?

Answer

In a business combination, the net assets acquired (if the acquisition is of net assets) or the entity over which control is obtained (if the acquisition is of equity interests) must constitute a business. ASC 805-10-20 defines a business as follows:

An 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 to help entities identify what constitutes a business:

55-4 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. The three elements of a business are defined as follows:

- a. Input. Any economic resource that creates, or has the ability to create, outputs when one or more processes are applied to it. Examples include long-lived assets (including intangible assets or rights to use long-lived assets), intellectual property, the ability to obtain access to necessary materials or rights, and employees.
- b. Process. Any system, standard, protocol, convention, or rule that when applied to an input or inputs, creates or has the ability to create outputs. Examples include strategic management processes, operational processes, and resource management processes. These processes typically are documented, but an organized workforce having the necessary skills and experience following rules and conventions may provide the necessary processes that are capable of being applied to inputs to create outputs. Accounting, billing, payroll, and other administrative systems typically are not processes used to create outputs.
- c. Output. The result of inputs and processes applied to those inputs that provide or have the ability to provide a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants.

55-5 To be capable of being conducted and managed for the purposes defined, an integrated set of activities and assets requires two essential elements — inputs and processes applied to those inputs, which together are or will be used to create outputs. However, 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.

55-6 The nature of the elements of a business varies by industry and by the structure of an entity's operations (activities), including the entity's stage of development. Established businesses often have many different types of inputs, processes, and outputs, whereas new businesses often have few inputs and processes and sometimes only a single output (product). Nearly all businesses also have liabilities, but a business need not have liabilities.

55-7 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. Those factors include, but are not limited to, whether the set:

- a. Has begun planned principal activities
- b. Has employees, intellectual property, and other inputs and processes that could be applied to those inputs
- c. Is pursuing a plan to produce outputs
- d. Will be able to obtain access to customers that will purchase the outputs.

Not all of those factors need to be present for a particular integrated set of activities and assets in the development stage to qualify as a business.

55-8 Determining whether a particular set of assets and activities is a business should be based on whether the integrated set is capable of being conducted and managed as a business by a market participant. Thus, in evaluating whether a particular set is a business, it is not relevant whether a seller operated the set as a business or whether the acquirer intends to operate the set as a business.

55-9 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.

The guidance in ASC 805-10-55 does not constitute a definitive checklist; an entity must use significant judgment and consider all facts and circumstances when assessing whether a group of assets constitutes 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. However, if all of the inputs and processes necessary to create outputs were not acquired, or if the set is not currently producing outputs, further consideration is necessary. For the set to qualify as a business, an entity does not necessarily have to acquire all of the inputs and processes necessary to make outputs. 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. 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.

Example 1

Pharma Co. enters into a worldwide license, manufacturing, and distribution agreement with Biotech Co. for a compound in preclinical development. Pharma Co. receives the right to manufacture, market, and distribute the compound in perpetuity if or 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, R&D 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.

Example 4

Pharma Co. acquires the outstanding shares of Biotech Co., a small entity that does not yet have a marketed product. Biotech Co.'s operations include R&D activities on several preclinical compounds that it is researching. Biotech Co. has employees performing the R&D activities who have previously demonstrated the ability to generate additional preclinical compounds through their research.

Pharma Co. concludes that Biotech Co.'s ability to generate additional compounds is an important factor in demonstrating that processes, in addition to inputs, were acquired. Although the acquired compounds may not be "capable of" generating a return individually because of the low probability of technical and regulatory success associated with early-stage compounds, Pharma Co. concludes that because of the inputs and processes obtained, the acquired set of assets and activities are capable of generating a return and the acquired set **is** a business.

Example 5

Pharma Co. acquires the outstanding shares of Biotech Co., a small entity that does not yet have a marketed product. Biotech Co.'s operations consist solely of researching one compound that has completed phase 1 clinical trials. Pharma Co. acquires only the intellectual property and know-how related to phase 1 activities and a manufacturing agreement for clinical supply of the active pharmaceutical ingredient. Pharma Co. does not acquire any employees or other assets and will need to design and conduct phase 2 clinical trials.

Because Pharma Co. did not acquire any employees or any inputs other than the intellectual property and clinical supply manufacturing agreement, Pharma Co. concludes that the acquired set is **not** a business.

Thinking It Through

For life sciences entities, 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.

Acquiring Net Assets or Equity Interests That Do Not Meet the Definition of a Business

M&A transactions that do not meet the definition of a business must be accounted for as an asset acquisition. As discussed below, in such transactions, the accounting requirements related to transaction costs, measurement of assets acquired and liabilities assumed, and recognition of intangible assets may differ from those for a business combination.

ASC 805-10-25-1 states, in part:

An entity shall determine whether a transaction or other event is a business combination by applying the definition in [ASC 805-10], which requires that the assets acquired and liabilities assumed constitute a business. If the assets acquired are not a business, the reporting entity shall account for the transaction or other event as an asset acquisition.

In addition, ASC 350-30-25-2 states that "the cost of a group of assets acquired in a transaction other than a business combination or an acquisition by a not-for-profit entity shall be allocated to the individual assets acquired based on their **relative** fair values and shall not give rise to goodwill" (emphasis added).

The accounting requirements for an acquisition of net assets or equity interests that is not deemed to be a business combination will differ in certain respects from the accounting requirements for a business combination.

Question

What are the key differences between the accounting for a business combination and the accounting for an acquisition of an asset group determined not to be a business?



Answer

The following table summarizes these differences:

Subject	Business Combination	Acquisition of an Asset Group Determined Not to Be a Business
Cost of the acquisition	<p>ASC 805-30-30-7 states:</p> <p>The consideration transferred in a business combination shall be measured at fair value, which shall be calculated as the sum of the acquisition-date fair values of the assets transferred by the acquirer, the liabilities incurred by the acquirer to former owners of the acquiree, and the equity interests issued by the acquirer. (However, any portion of the acquirer's share-based payment awards exchanged for awards held by the acquiree's employees that is included in consideration transferred in the business combination shall be measured in accordance with [ASC] 805-20-30-21 rather than at fair value.) Examples of potential forms of consideration include the following:</p> <ol style="list-style-type: none"> Cash Other assets A business or a subsidiary of the acquirer Contingent consideration (see [ASC] 805-30-25-5 through 25-7) Common or preferred equity instruments Options Warrants Member interests of mutual entities. 	<p>ASC 805-50-30-1 states, in part:</p> <p>Assets are recognized based on their cost to the acquiring entity, which generally includes the transaction costs of the asset acquisition, and no gain or loss is recognized unless the fair value of noncash assets given as consideration differs from the assets' carrying amounts on the acquiring entity's books. [Emphasis added]</p>
Measuring the assets acquired and liabilities assumed	<p>ASC 805-20-30-1 states that the "acquirer shall measure the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree at their acquisition-date fair values."</p> <p>ASC 805-30-30-1 indicates that goodwill should be recorded as the sum of the (1) consideration transferred, (2) fair value of any noncontrolling interest, and (3) fair value of the acquirer's previously held interest in the acquiree, if any, less the acquisition-date fair value of the net assets acquired.</p>	<p>ASC 805-50-30-3 states, in part:</p> <p>Acquiring assets in groups requires not only ascertaining the cost of the asset (or net asset) group but also allocating that cost to the individual assets (or individual assets and liabilities) that make up the group. The cost of such a group is determined using the concepts described in [ASC 805-50-30-1 and 30-2]. The cost of a group of assets acquired in an asset acquisition shall be allocated to the individual assets acquired or liabilities assumed based on their relative fair values and shall not give rise to goodwill.</p>
Recognition of intangible assets	<p>ASC 805-20-25-10 states, in part, that the "acquirer shall recognize separately from goodwill the identifiable intangible assets acquired in a business combination. An intangible asset is identifiable if it meets either the separability criterion or the contractual-legal criterion described in the definition of identifiable" (emphasis added).</p>	<p>ASC 350-30-25-1 states that an "intangible asset that is acquired either individually or with a group of other assets [but not those acquired in a business combination] shall be recognized." Further, ASC 350-30-25-4 states that "[i]ntangible assets that are acquired individually or with a group of assets in a transaction other than a business combination or an acquisition by a not-for-profit entity may meet asset recognition criteria in FASB Concepts Statement No. 5, <i>Recognition and Measurement in Financial Statements of Business Enterprises</i>, even though they do not meet either the contractual-legal criterion or the separability criterion (for example, specially-trained employees or a unique manufacturing process related to an acquired manufacturing plant). . . . Thus, those assets shall be recognized as intangible assets."</p>

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. Contingent consideration is measured in accordance with other applicable GAAP, such as ASC 450 and ASC 815.

Measuring the Assets Acquired and Liabilities Assumed

In accordance with ASC 805, an acquirer measures assets acquired and liabilities assumed in a business combination that arise from contingencies at their acquisition-date fair value if it can be determined during the measurement period. If fair value cannot be determined, the asset or liability should be measured in accordance with ASC 450. ASC 805-20-25-20B states that if the criteria for recognition at fair value or in accordance with ASC 450 are not met “at the acquisition date using information that is available during the measurement period about facts and circumstances that existed as of the acquisition date, the acquirer shall not recognize an asset or liability as of the acquisition date.” In addition, “[i]n periods after the acquisition date, the acquirer shall account for an asset or a liability arising from a contingency that does not meet the recognition criteria at the acquisition date in accordance with other applicable GAAP, including [ASC] 450, as appropriate.”

In an asset acquisition, acquired contingent assets and assumed contingent liabilities are accounted for in accordance with ASC 450, generally resulting in (1) no recognition of acquired contingent assets and (2) recognition of a contingent liability only if it is probable that a liability has been incurred and the amount can be reasonably estimated.

Further, in an asset acquisition, an entity allocates the cost of the assets and liabilities (asset group) on the basis of their relative fair values and is not permitted to recognize any goodwill. If the cost exceeds the fair value of the asset group, the entity allocates the difference pro rata on the basis of relative fair values to increase the assets acquired, except for financial assets (other than investments accounted for under the equity method) and assets subject to fair value impairment testing, such as inventories and indefinite-lived intangible assets, since increasing the value of such assets would most likely result in an impairment as of the next testing date.

If the fair value of the asset group exceeds its cost, the entity allocates the difference pro rata on the basis of relative fair values to decrease the assets acquired, except for financial assets (other than investments accounted for under the equity method) and assets subject to fair value impairment testing. If, however, the asset acquisition in which the fair value of the asset group exceeds its cost also involves a contingent consideration arrangement, the entity should analogize to the guidance in ASC 323-10-25-2A and ASC 323-10-30-2B on recognizing contingent consideration in the acquisition of equity method investments (i.e., assuming that the contingent consideration arrangement does not meet the definition of a derivative; if the arrangement meets the definition of a derivative, it would be accounted for in accordance with ASC 815). The guidance in ASC 323-10-25-2A and ASC 323-10-30-2B states that if an entity acquires an equity method investment in which the fair value of its share of the investee’s net assets exceeds its initial cost and the agreement includes contingent consideration, the entity must recognize a liability equal to the lesser of:

- The maximum amount of contingent consideration.
- The excess of its share of the investee’s net assets over the initial cost measurement.

As with acquisitions of equity method investments, a cost accumulation model applies to asset acquisitions. Thus, the guidance above also applies to asset acquisitions by analogy. Therefore, if an entity acquires a group of assets in which the fair value of the net assets exceeds its initial cost and the agreement includes contingent consideration, the entity must recognize a liability equal to the lesser of:

- The maximum amount of contingent consideration.
- The excess of the fair value of the net assets acquired over the initial cost measurement.

Once recognized, the contingent consideration liability is not derecognized until the contingency is resolved and the consideration is issued or becomes issuable. In accordance with the requirements of ASC 323-10-35-14A for equity method investments, the entity recognizes any excess of the contingent consideration issued or issuable, over the amount that was initially recognized as a liability, as an additional cost of the asset acquisition. If the amount initially recognized as a liability exceeds the contingent consideration issued or issuable, the entity recognizes that amount as a reduction of the cost of the asset acquisition.

Recognition of Intangible Assets

Under ASC 805, an assembled workforce is not an intangible asset that can be recognized apart from goodwill. In an asset acquisition, however, an assembled workforce may exist and may have to be recognized.

ASC 805 requires assets acquired in a business combination that are used in R&D activities (i.e., in-process R&D (IPR&D)) to be (1) initially recognized as indefinite-lived intangible assets and (2) measured at fair value. In an asset acquisition, the cost of acquired intangible assets obtained from others, when these assets are to be used in R&D activities that do not have an alternative future use, is charged to expense in accordance with ASC 730.

Example 1 — Allocating the Cost of an Asset Acquisition When Cost Exceeds Fair Value

Company A acquires two assets from Company B for \$120. The collective fair value of the assets is \$100. Because the assets acquired were determined not to constitute a business, the \$20 excess of the cost of the acquired assets (\$120) over the amounts assigned to the identifiable assets (\$100) must be allocated to the assets and cannot be recognized as goodwill. The following table illustrates the allocation of the cost of the assets on the basis of relative fair values:

	Initial Fair Value Measurement	Allocation	Total
Asset A	\$ 10	\$ 2	\$ 12
Asset B	90	18	108
Total	<u>\$ 100</u>	<u>\$ 20</u>	<u>\$ 120</u>

Example 2 — Allocating the Cost of an Asset Acquisition When Fair Value Exceeds Cost

Company A acquires two assets from Company B for \$120 and an agreement to provide additional cash consideration of \$30 in one year if a specified future event occurs. The fair value of the assets is \$140, collectively, and the assets acquired do not constitute a business. Company A recognizes a contingent consideration liability of \$20, which is the lesser of the (1) maximum amount of the contingent consideration or (2) excess of the fair value of the net assets over the initial cost. The following table shows the amounts recognized as of the acquisition date:

	Initial Fair Value Measurement	Difference	Total
Asset A	\$ 40	\$ —	\$ 40
Asset B	100	—	100
Contingent consideration	—	(20)	(20)
Total	<u>\$ 140</u>	<u>\$ (20)</u>	<u>\$ 120</u>

Example 3 — Allocating the Cost of an Asset Acquisition of IPR&D When Fair Value Exceeds Cost

Company A acquired exclusive license rights for a compound from Company B in a transaction accounted for as an asset acquisition. Company A paid an up-front fee of \$1 million and agreed to make a milestone payment of \$2 million to B upon regulatory approval of the compound.

Company A determined that the milestone payment does not represent a derivative. In addition, the fair value of the compound was determined to be in excess of the up-front consideration transferred as of the acquisition date.

Company A accounted for the acquisition of the license as IPR&D (i.e., expensed) because the compound is in early-stage development and has not received regulatory approval. Further, Company A concluded that it would not be appropriate to record any portion of the contingent milestone payment as of the acquisition date given the conclusion that the acquired license should be accounted for as IPR&D and expensed as of the acquisition date.

Question

In Example 3 above, given that the fair value of the compound acquired was greater than the up-front consideration transferred, how should A account for the contingent milestone payment upon acquisition?

Answer

When an asset acquisition causes the fair value of an asset group to exceed its cost and the acquisition involves a contingent consideration arrangement, the entity should recognize a liability equal to the lesser of:

- The maximum amount of contingent consideration.
- The excess of the fair value of the net assets acquired over the initial cost measurement.

Under existing guidance, it would appear that some portion of the milestone payment would be recorded as of the acquisition date given that the fair value of the compound was greater than the up-front consideration transferred. However, A concluded that such guidance is not applicable in this case because the acquisition of the license will be accounted for as IPR&D and therefore will be expensed as of the acquisition date. Further, applying the existing guidance would result in an unintended outcome in which the future milestone payment that otherwise would have been recorded upon the triggering event of the milestone (and most likely would be capitalized since the milestone payment is only triggered upon regulatory approval) would need to be expensed as IPR&D as of the acquisition date. In such a narrow fact pattern, in which the acquisition is entirely attributable to IPR&D that must be expensed as of the acquisition date, A's conclusion not to recognize the contingent milestone payment is reasonable under the circumstances. However, such a conclusion would generally not be appropriate when an asset acquisition involves (1) elements in addition to IPR&D and (2) a contingent consideration arrangement. In such cases, an entity would need to carefully assess all facts and circumstances.

IPR&D Intangible Assets Acquired in a Business Combination

Life sciences entities often contemplate opportunities for expanding their current portfolio of development-stage products by making strategic acquisitions. The accounting for costs associated with the purchase of such product rights currently in development as part of a business combination may vary significantly from the typical accounting treatment of R&D costs incurred by life sciences entities as part of their normal operations.

Before a business combination, an acquired entity may incur R&D expenditures that could result in the acquired entity's development of certain intangible assets that would be expensed as incurred in accordance with ASC 730 unless they had an alternative future use. That is, an acquired entity would probably not record any assets on its books before the consummation of a business combination related to R&D. To the extent that the acquired entity was using, or was planning to use, these unrecognized assets for R&D activities, the assets would represent acquired IPR&D to the acquirer.

Question

Should an entity recognize intangible assets apart from goodwill for IPR&D activities acquired in a business combination?

Answer

Yes. Under ASC 805 and ASC 350, the acquiring entity recognizes acquired IPR&D at fair value as of the acquisition date and subsequently accounts for it as an indefinite-lived intangible asset until completion or abandonment of the associated R&D efforts.

For IPR&D to be recognized as of the acquisition date, the costs incurred by the acquiree must be for R&D activities within the scope of ASC 730. The Codification Master Glossary defines the term “research and development” as follows:

Research is planned search or critical investigation aimed at discovery of new knowledge with the hope that such knowledge will be useful in developing a new product or service (referred to as product) or a new process or technique (referred to as process) or in bringing about a significant improvement to an existing product or process.

Development is the translation of research findings or other knowledge into a plan or design for a new product or process or for a significant improvement to an existing product or process whether intended for sale or use. It includes the conceptual formulation, design, and testing of product alternatives, construction of prototypes, and operation of pilot plants.

ASC 730-10-55-1 lists the following examples of activities that are within the scope of ASC 730 (unless conducted for others under a contractual arrangement):

- a. Laboratory research aimed at discovery of new knowledge
- b. Searching for applications of new research findings or other knowledge
- c. Conceptual formulation and design of possible product or process alternatives
- d. Testing in search for or evaluation of product or process alternatives
- e. Modification of the formulation or design of a product or process
- f. Design, construction, and testing of preproduction prototypes and models
- g. Design of tools, jigs, molds, and dies involving new technology
- h. Design, construction, and operation of a pilot plant that is not of a scale economically feasible to the entity for commercial production
- i. Engineering activity required to advance the design of a product to the point that it meets specific functional and economic requirements and is ready for manufacture
- j. Tools used to facilitate research and development or components of a product or process that are undergoing research and development activities.

ASC 730-10-55-2 lists the following examples of activities that are outside the scope of ASC 730:

- a. Engineering follow-through in an early phase of commercial production
- b. Quality control during commercial production including routine testing of products
- c. Trouble-shooting in connection with break-downs during commercial production
- d. Routine, ongoing efforts to refine, enrich, or otherwise improve upon the qualities of an existing product
- e. Adaptation of an existing capability to a particular requirement or customer’s need as part of a continuing commercial activity
- f. Seasonal or other periodic design changes to existing products
- g. Routine design of tools, jigs, molds, and dies
- h. Activity, including design and construction engineering, related to the construction, relocation, rearrangement, or start-up of facilities or equipment other than the following:
 1. Pilot plants (see [ASC 730-10-55-1(h)])
 2. Facilities or equipment whose sole use is for a particular research and development project (see [ASC 730-10-25-2(a)]).
- i. Legal work in connection with patent applications or litigation, and the sale or licensing of patents.

R&D activities are only considered to be within the scope of ASC 730 if such activities are not “conducted for others under a contractual arrangement.” If R&D activities are conducted for others under a contractual arrangement, the costs of such activities should not be recognized as part of the acquired IPR&D. Further, questions have arisen regarding whether a fully outlicensed R&D project acquired in a business combination constitutes acquired IPR&D.

Example

On June 30, 20X9, Company A, a calendar-year-end company, acquires Company B in a transaction accounted for as a business combination. Before the acquisition, B incurs significant costs related to the R&D of a new line of products, all of which it expensed as incurred under ASC 730. Company A plans to continue these R&D efforts in hopes of releasing the new line of products into the market.

Using the acquisition method of accounting, and in a manner consistent with the fair value measurement guidance in ASC 820, A determines that the fair value of the acquired IPR&D assets is \$10 million. Therefore, as of the acquisition date, A would record an indefinite-lived intangible asset of \$10 million.

After the acquisition date, A would account for all additional costs it incurs in connection with this project under ASC 730 (i.e., such costs would generally be expensed as incurred).

Identifying IPR&D

Question

What considerations should an entity take into account when identifying IPR&D?

Answer

The AICPA’s existing IPR&D practice aid, issued in 2013, includes guidance on identifying IPR&D. The practice aid observes that “incompleteness” is an essential characteristic of IPR&D. Paragraphs 2.54 and 2.55 of the practice aid state:

At some point before commercialization (that is, before earning revenue), and possibly before the end of the development or preproduction stages, the [AICPA IPR&D Task Force (the “task force”)] believes that the IPR&D project is no longer considered incomplete for accounting purposes (that is, ultimate completion of the project has occurred), and an asset resulting from R&D emerges from what was previously an asset used in R&D.

The attribute of incompleteness with respect to a specific IPR&D project acquired as part of a business combination suggests that there are remaining technological or engineering risks or regulatory approvals.

Further, paragraph 2.56 of the practice aid states:

Both of the following factors would need to be considered when evaluating whether activities making up a specific R&D project are incomplete at the acquisition date:

- a. Whether the reporting entity expects¹¹ to incur more than *de minimis* future costs related to the acquired project that would qualify as R&D costs under FASB ASC 730-10
- b. Whether additional steps or milestones in a specific R&D project remain for the reporting entity, such as successfully overcoming the remaining risks or obtaining regulatory approvals related to the results of the R&D activities.

¹¹ “An entity may choose to evaluate its expectations, but is not required to do so, by employing a probability-weighted expected cash flow method. For example, an entity may believe that it is 50-percent likely that it will obtain regulatory approval for the product derived from its [R&D] efforts; if such approval is obtained, the entity does not expect further cash outflows for additional R&D activities. The same entity believes that if regulatory approval is not obtained (also a 50-percent likely outcome) that it will incur \$100 of additional R&D costs. In this simple example, the entity expects to spend \$50 on future R&D costs. That amount may or may not be *de minimis*.”

The AICPA guide describes “incompleteness” as a key attribute of IPR&D and specifically addresses outlicensing arrangements. Paragraph 2.10 states, in part:

Outlicensed. If the reporting entity intends to outlicense an acquired intangible asset (or acquires an already outlicensed intangible asset) but plans to play an active role in the development of the outlicensed asset (for example, under a *collaborative arrangement* with another party), the task force believes that such asset would be considered “used in R&D activities.” [Footnote omitted] This is because the reporting entity will use the acquired asset in its R&D activities jointly with another party.

However, the task force believes that if the reporting entity intends to outlicense an acquired intangible asset and does not plan to be actively involved in its development, then such asset would not be considered “used in R&D activities.” If such *outlicensing arrangement* was in place at the time of business combination, the outlicensed asset would not be considered “used in R&D activities;” it would be considered a contract based intangible asset, provided it meets the recognition criteria described in the “Asset Recognition Criteria” section in paragraphs 2.06–.07.

In light of the above, we expect that there will be circumstances in which an outlicensed R&D project should be accounted for as a contract-based intangible asset (as defined in ASC 805-20-55-31) rather than an IPR&D asset. This determination is important because an R&D activity that constitutes IPR&D is accounted for as an indefinite-lived intangible asset (until completion or abandonment of the R&D efforts). In contrast, a contract-based intangible would typically be accounted for as a definite-lived intangible asset (subject to amortization).

For example, assume that the intellectual property associated with an R&D project has been fully outlicensed to a third party upon acquisition. The third party is responsible for planning and executing the remaining R&D activities, achieving the R&D advances, and directly incurring the related R&D costs. The acquirer’s (and the combined enterprise’s) interest in the intellectual property is passive since the acquirer stands only to receive contractually obligated milestones and royalties on the basis of the success of the third party’s R&D efforts. In this example, the acquirer will not have any input into the R&D activities, R&D protocols, regulatory approval process, or any aspects of commercialization (e.g., manufacturing, sales, marketing, pricing) being performed by the third party. Further, the acquirer will not incur any costs related to the outlicensed property that meet the definition of R&D under ASC 730. It would therefore be appropriate to account for the R&D project as a contract-based intangible asset; accordingly, the acquirer would determine the useful life of the asset and the method of amortization.

Thinking It Through

To reach such accounting conclusions, an entity must carefully analyze the nature and extent of the licensor’s ongoing involvement with the R&D project. In certain outlicensing arrangements, the licensor retains some level of continuing involvement with the intellectual property. For example, the licensor may have some obligation to reimburse R&D costs incurred by the third party or may continue to have input into the ongoing R&D activities. In such cases, it might be appropriate to account for the R&D activities as IPR&D (provided that all other facts and circumstances have been considered).

Also, if an entity acquires IPR&D in a business combination that it does not intend to put to the highest and best use (e.g., it has plans to discontinue the R&D project after the acquisition even though a marketplace participant would continue the R&D efforts), it would still be required to recognize an intangible asset at fair value in applying acquisition-method accounting.

Accounting for Acquired IPR&D Assets After Recognition in a Business Combination

Question

Under ASC 805, the acquiring entity recognizes IPR&D assets at fair value as of the acquisition date. How does an entity account for acquired IPR&D assets after those assets are recognized in a business combination?

Answer

Under ASC 350, the entity subsequently accounts for the acquired IPR&D assets as indefinite-lived intangible assets until completion or abandonment of the associated R&D efforts. ASC 350-30-35-17A further states, in part:

During the period that [the acquired IPR&D intangible] assets are considered indefinite lived, they shall not be amortized but shall be tested for impairment in accordance with [ASC] 350-30-35-18 [and] 35-19. Once the research and development efforts are completed or abandoned, the entity shall determine the useful life of the assets based on the guidance in [ASC 350-30-35]. Consistent with the guidance in [ASC] 360-10-35-49, intangible assets acquired in a business combination or an acquisition by a not-for-profit entity that have been temporarily idled shall not be accounted for as if abandoned.

While acquired assets related to IPR&D activities of an acquiree in a business combination may be recognized as intangible assets, ASC 805 and ASC 350 do not change the accounting for R&D expenditures incurred outside of a business combination. Therefore, subsequent R&D expenditures related to the acquired IPR&D intangible assets should generally be expensed as incurred.

Example 1

On June 30, 20X1, Company A acquires Company B in a transaction accounted for as a business combination. Before the acquisition, B had incurred significant costs related to the R&D of a new product, all of which it expensed as incurred in accordance with ASC 730. Company A plans to continue these R&D efforts in hopes of commercializing the product in the future.

Using the acquisition method of accounting, and in a manner consistent with the fair value measurement guidance in ASC 820, A determines that the fair value of the acquired IPR&D assets is \$10 million. Therefore, as of the acquisition date, A would record an indefinite-lived intangible asset of \$10 million.

On July 1, 20Y2, A concludes that development of the new product is no longer feasible and decides to abandon its project because there is no alternative future use for the acquired IPR&D assets.

From June 30, 20X1, to June 30, 20Y2, Company A appropriately tested the acquired IPR&D assets (\$10 million) for impairment in accordance with ASC 350-30-35-18 and did not record any impairment losses.

Because of its plans to abandon the project and the fact that the IPR&D assets have no alternative future use, A would expense the entire IPR&D asset balance of \$10 million on July 1, 20Y2 (the date of abandonment), in the income statement.

Example 2

Assume the same facts as in Example 1, except that A successfully completes its IPR&D project on July 1, 20Y2, and has developed a commercially viable product that it intends to sell in the marketplace.

In this case, A must assess the useful life of the acquired IPR&D assets as of July 1, 20Y2 (the date the IPR&D project is successfully completed), and amortize the assets over the related products' useful lives. That is, the acquired IPR&D assets' useful life is now finite rather than indefinite. In addition, the reclassification to a finite useful life triggers a required impairment test in accordance with ASC 350-30-35-17 as of July 1, 20Y2.

Accounting for the Settlement of Preexisting Relationships

The acquirer and acquiree may have a preexisting relationship, such as a collaboration agreement to codevelop or copromote a particular compound.

Question

How should an entity account for a business combination's settlement of a preexisting relationship?

Answer

ASC 805-10-55-21 states:

If the business combination in effect settles a preexisting relationship, the acquirer recognizes a gain or loss, measured as follows:

- a. For a preexisting noncontractual relationship, such as a lawsuit, fair value
- b. For a preexisting contractual relationship, the lesser of the following:
 1. The amount by which the contract is favorable or unfavorable from the perspective of the acquirer when compared with pricing for current market transactions for the same or similar items. An unfavorable contract is a contract that is unfavorable in terms of current market terms. It is not necessarily a loss contract in which the unavoidable costs of meeting the obligations under the contract exceed the economic benefits expected to be received under it.
 2. The amount of any stated settlement provisions in the contract available to the counterparty to whom the contract is unfavorable. If this amount is less than the amount in (b)(1), the difference is included as part of the business combination accounting.

The gain or loss on the preexisting relationship is considered a transaction that is separate and apart from the business combination.

Thinking It Through

Companies should assess whether the preexisting relationship is held at fair value before acquisition. If so, no gain or loss would be recognized. In making this determination, a company must carefully assess both fair value and what is being acquired. For example, certain collaborative arrangements may not be held at fair value (e.g., when there are equity investments in the acquiree). In such cases, a gain or loss should be recognized for the difference between the fair value and carrying value recorded.

Accounting for Contingent Consideration

Question

How should an entity account for contingent consideration in a business combination?

Answer

In accordance with ASC 805-30-25, contingent consideration is recorded at fair value as part of the total consideration transferred by the acquirer. The acquirer must distinguish between contingent consideration (see ASC 805-10-20) and preexisting contingencies assumed in the acquisition (see ASC 450-10-20). The fair value of contingent consideration is considered part of the purchase price and recorded on the balance sheet either as a liability or within equity (or, less commonly, as an asset). Contingent consideration arrangements classified as liabilities must be remeasured in each reporting period, with gains and losses recorded in earnings. Contingent consideration arrangements classified in equity are not remeasured, even if the contingent event does not occur.

Thinking It Through

A contingent consideration arrangement in a business combination between two life sciences companies could involve future FDA approval of a pharmaceutical product. In this case, a company may need to use considerable judgment in determining the fair value of the consideration, particularly when assessing the probability of the FDA approval.

Divestitures

The determination of whether a group of assets represents a business is important not only in acquisitions but also in divestitures. Specifically, in divestiture transactions related to the disposal of a business, a company has the option of electing different accounting alternatives and using them as a precedent for future transactions. The accounting policy described in the Q&A below is relevant only to groups of assets that meet the definition of a business. If assets are sold, it would not be appropriate to recognize contingent consideration before it is realized.

Seller's (Parent's) Accounting for Contingent Consideration Upon Deconsolidation of a Subsidiary or Derecognition of a Group of Assets That Is a Business

Under a contingent consideration arrangement, a buyer is obligated to transfer additional consideration to a seller as part of the exchange for control of the acquiree if a specified future event occurs or a condition is met. Entities must evaluate the nature of each arrangement to determine whether contingent future payments are (1) part of the exchange for control (i.e., contingent consideration) or (2) separate transactions. Examples of contingent payment arrangements that are separate transactions include, but are not limited to, payments related to compensation for services, consulting contracts, profit-sharing agreements, property lease agreements, and executory contracts.

This Q&A does not address contingent payment arrangements that are separate transactions. That is, this Q&A only addresses arrangements in which the payment is contingent consideration.

Further, it is assumed in this Q&A that the seller has determined that the arrangement does not meet the definition of a derivative instrument. If the arrangement met the definition of a derivative, it would be accounted for under ASC 815.

Question

How should a seller account for the contingent consideration arrangement upon deconsolidation of its subsidiary or derecognition of a group of assets that is a business?

Answer

This topic is discussed in EITF Issue 09-4. At its [September 9–10, 2009, meeting](#), the EITF considered the two approaches discussed below with respect to a seller's accounting for a contingent consideration arrangement upon deconsolidation of a subsidiary or derecognition of a group of assets that meets the definition of a business; however, the Task Force did not reach a consensus on this Issue. Accordingly, in the absence of future standard setting, there may be diversity in practice regarding a seller's accounting for a contingent consideration arrangement. Nevertheless, entities should establish an accounting policy for the initial and subsequent measurement of these types of arrangements. The seller should apply the chosen option to all future transactions. In addition, if an entity believes that it can support an alternative accounting treatment for a specific contingent consideration arrangement (other than the two approaches considered by the EITF), it should consult its accounting advisers.

Approach 1

The seller includes the initial fair value of any contingent consideration arrangement in the overall gain or loss on deconsolidation of a subsidiary. Supporters of this approach point to ASC 810-10-40-5, which states that the seller (parent) should include the "fair value of **any** consideration received" (emphasis added) when calculating the gain or loss on deconsolidation of a subsidiary. Accordingly, the "consideration received" should include the fair value of any contingent consideration arrangements between the seller and buyer. Under this approach, the seller would recognize a contingent consideration receivable for the future amounts due from the buyer.

If the seller adopts this approach to initially account for a contingent consideration agreement, it should elect an accounting policy to (1) subsequently remeasure the contingent consideration at fair value as of the end of each reporting period or (2) subsequently apply the gain contingency guidance in ASC 450-30.

Approach 2

The seller accounts for the contingent consideration arrangement as a gain (or loss) contingency in accordance with ASC 450. This approach is consistent with the accounting that entities applied to such transactions before the FASB issued Statement 160. Under this approach, the seller typically recognizes the contingent consideration receivable in earnings after the contingency is resolved. Accordingly, to determine the initial gain or loss on deconsolidation of a subsidiary, the seller would not include an amount related to the contingent consideration arrangement as part of the consideration received unless the criteria in ASC 450 are met. Supporters of this approach believe that the FASB did not intend to change practice when it issued Statement 160.

If the seller selects this approach to initially account for a contingent consideration agreement, it should continue to apply this approach in subsequent periods until the contingency is resolved.

Example

Parent A has a wholly owned subsidiary with a carrying amount of \$100. Parent A decides to sell 100 percent of this subsidiary to Company B, a third-party buyer. As part of the purchase agreement, B agrees to pay A (1) \$150 upon the close of the transaction and (2) an additional \$50 if the subsidiary’s earnings exceed a specified level for the 12-month period after the close of the transaction. Upon the close of the transaction, A calculates the fair value of the contingent consideration portion of the arrangement to be \$30. In addition, the arrangement does not meet the definition of a derivative.

Parent A would compute its initial gain on the sale, which would be recognized upon the close of the transaction, under the two approaches as follows:

	Approach 1	Approach 2
Cash proceeds	\$ 150	\$ 150
Contingent consideration receivable	<u>30</u>	<u>—</u>
Total consideration	180	150
Less: subsidiary’s carrying amount	<u>(100)</u>	<u>(100)</u>
Initial gain on sale	<u>\$ 80</u>	<u>\$ 50</u>

Recently Issued Accounting Standards Updates

Simplifying the Accounting for Measurement-Period Adjustments

Background

On September 25, 2015, the FASB issued [ASU 2015-16](#), which amends the guidance in ASC 805 on the accounting for measurement-period adjustments. The ASU was issued as part of the FASB’s simplification initiative in response to stakeholder feedback that restating prior periods to reflect adjustments made to provisional amounts recognized in a business combination adds cost and complexity to financial reporting but does not significantly improve the usefulness of the information provided to users.

Key Provisions of the ASU

Under previous guidance, when an acquirer identified an adjustment to provisional amounts during the measurement period, the acquirer was required to revise comparative information for prior periods, including making any change in depreciation, amortization, or other income effects recognized in completing the initial accounting, as if the accounting for the business combination had been completed as of the acquisition date.

The ASU requires an acquirer to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The effect on earnings of changes in depreciation or amortization, or other income effects (if any) as a result of the change to the provisional amounts, calculated as if the accounting had been completed as of the acquisition date, must be recorded in the reporting period in which the adjustment amounts are determined rather than retrospectively.

Thinking It Through

Although the ASU changes the accounting for measurement-period adjustments, it does not change the definition of a measurement-period adjustment, which is an adjustment to the amounts provisionally recognized for the consideration transferred, the assets acquired, and the liabilities assumed as a result of “new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date.” Errors, information received after the measurement period ends, or information received about events or circumstances that did not exist as of the acquisition date are not measurement-period adjustments.

Disclosure Requirements

The ASU also requires that the acquirer present separately on the face of the income statement, or disclose in the notes, the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date.

Effective Date and Transition

For public business entities, the ASU is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. For all other entities, the ASU is effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The ASU must be applied prospectively to adjustments to provisional amounts that occur after the effective date. Early application is permitted for financial statements that have not been issued.

The only disclosures required at transition will be the nature of and reason for the change in accounting principle. An entity should disclose that information in the first annual period of adoption and in the interim periods within the first annual period if there is a measurement-period adjustment during the first annual period in which the changes are effective.

For more information about the ASU, see Deloitte’s September 30, 2015, *Heads Up*.

Accounting Alternatives for Private Companies

The following guidance (developed in 2014 by the Private Company Council (PCC)) is effective in 2015 or 2016:

- *Goodwill* — On January 16, 2014, the FASB issued [ASU 2014-02](#), which allows a private company² to use a simplified approach to account for goodwill after an acquisition. Under that approach, an entity would (1) amortize goodwill on a straight-line basis, generally over 10 years; (2) test goodwill for impairment only when a triggering event occurs; and (3) make an accounting policy election to test for impairment at either the entity level or the

² An entity other than a “public business entity,” a “not-for-profit entity,” or an employee benefit plan within the scope of ASC 960 through ASC 965 on plan accounting.

reporting-unit level. The ASU also eliminates step 2 of the goodwill impairment test; as a result, an entity would measure goodwill impairment as the excess of the entity's (or reporting unit's) carrying amount over its fair value. An entity that elects the simplified approach should apply the ASU's guidance prospectively to all goodwill existing as of the beginning of the period of adoption and any goodwill arising from subsequent acquisitions. The ASU is effective for annual periods beginning after December 15, 2014, and interim periods with annual periods beginning after December 15, 2015; early adoption was permitted. See Deloitte's January 27, 2014, *Heads Up* for more information.

- *Intangibles* — On December 23, 2014, the FASB issued [ASU 2014-18](#), which gives private companies an exemption from having to recognize certain intangible assets for (1) assets acquired in a business combination or (2) investments accounted for under the equity method or upon the adoption of fresh-start accounting. Specifically, an entity would not be required to separately recognize noncompete agreements and certain customer-related intangible assets within the scope of the ASU. Because the amounts associated with these items would be subsumed into goodwill, an entity that elects this accounting alternative would also be required to adopt ASU 2014-02 (see discussion above), resulting in the amortization of goodwill. Entities that elect the alternative should apply the ASU prospectively to the first eligible transaction within the scope of the ASU that occurs in the annual period beginning after December 15, 2015 (with early adoption permitted), and all transactions thereafter. See Deloitte's December 30, 2014, *Heads Up* for more information.

SEC Comment Letter Themes

Business Combinations — Registrants in the Life Sciences Industry

Example of an SEC Comment

You state that you acquired no significant processes in your . . . acquisition of all of the outstanding shares of [Company A]. Please provide your analysis supporting this conclusion and that this was not an acquisition of a business. Refer to ASC 805-10-55-4 through [55-9].

As previously noted, the life sciences industry in recent years has seen an increase in M&A activity. While many entities in the industry have sought ways to expand their pipeline of products in development or acquire additional commercial products, others have explored how to generate additional returns on assets that are no longer a strategic focus.

Accounting for a transaction as a business combination differs significantly from accounting for a transaction as an asset acquisition, as described in [Determining Whether an Asset Group Constitutes a Business](#) above. Consequently, when acquisitions occur, it is important to determine whether what is being acquired meets the definition of a business under ASC 805. Accordingly, the SEC staff often issues comments related to whether the acquired set meets the definition of a business and further inquires about the basis for the registrant's conclusion.

In addition, in business combinations involving the acquisition of intangible assets, acquirers must determine the useful life of each intangible asset acquired. 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 company's patent expires or a high barrier to market entry even after the company's patent expires. Therefore, the SEC staff has asked registrants to provide additional analysis that explains the basis for their conclusions about the useful lives of acquired intangible assets.

Business Combinations — Registrants Across Industries

Below are examples of SEC staff comments that registrants across a number of industries have received regarding their accounting for business combinations.

Purchase Price Allocation

Example of an SEC Comment

In regard to your preliminary purchase price allocation . . . , please provide further supporting disclosure for each purchase price adjustment to each tangible and intangible asset acquired and liability assumed. This disclosure should explain in greater detail what the adjustment represents and how the increase or decrease was determined, including a brief explanation of the factors and assumptions involved in the calculation. For example, please disclose and explain how you determined the increase in property, plant and equipment, franchises and customer relationships.

The SEC staff frequently asks registrants how they have assigned amounts to assets acquired and liabilities assumed in business combinations. In particular, the SEC staff asks registrants that have recorded a significant amount of goodwill why they have not attributed value to identifiable intangible assets. The SEC staff also compares disclosures provided in press releases, the business section, and MD&A to the purchase price allocation in the financial statements. For example, the SEC staff may ask why a registrant did not recognize a customer-related intangible asset if it discloses in MD&A that it acquired customers in a business combination. In addition, the SEC staff may ask detailed questions about (1) how a registrant determined that intangible assets would have finite or indefinite useful lives; (2) the useful lives of identified intangible assets determined to have finite useful lives; and (3) material revisions to the initial accounting for a business combination, including what significant assumptions have changed to support a revision to the value of intangible assets.

Contingent Consideration

Example of an SEC Comment

Please note that ASC 805-30-50-1(c) requires a description of contingent consideration arrangements in the financial statements including the basis for determining the amount of any payments. Also, disclosure of the changes in the range of outcomes and reasons for those changes is required to be disclosed in accordance with ASC 805-30-50-4. Given these disclosure requirements, please provide draft disclosure to be included in future filings to disclose both the nature and terms of the contingent consideration arrangement including the metrics which must be achieved for payments to occur, and the nature and timing of the changes in facts and circumstances that resulted in your reversal of the previously recorded expense for future incentive payments of \$[X] during the fourth quarter of the fiscal year ended February 1, 2014. As part of your revised disclosure, please also explain why your determination that the financial metrics would not be achieved did not occur until the fourth quarter of your fiscal year ended February 1, 2014.

The SEC staff often asks registrants to provide additional disclosures about the nature and terms of a contingent consideration arrangement and the conditions that must be met for the arrangement to become payable. Since ASC 805 requires entities to recognize contingent consideration at fair value as of the acquisition date, the staff may ask registrants to disclose how they determined the fair value of the contingent consideration. In addition, the staff may ask whether the change in the fair value of contingent consideration should be reflected as a retrospective adjustment to the amount of goodwill (i.e., if the adjustment is due to new information obtained during the measurement period about facts or circumstances that existed as of the acquisition date) or in current earnings under ASC 805-10-25-13 through 25-19 and ASC 805-10-30-3. The staff may also ask for disclosure of the total amount of contingent consideration that could become payable under the terms of the arrangement.

Disclosures

Example of an SEC Comment

Please revise [the notes] to disclose the amounts of revenue and earnings of [Company A] and [Company B] since the acquisition date which have been included in the consolidated income statement for the reporting period in which the acquisitions occurred. Also, please revise to disclose the revenue and earnings of the combined entity for the current reporting period as though the acquisition date for all business combinations that occurred during the period had been as of the beginning of the annual reporting period. Comparable information for the prior annual period should also be presented as if these acquisitions had occurred at the beginning of the comparable prior annual reporting period. Refer to the disclosure requirements outlined in ASC 805-10-50-2(h).

The SEC staff has commented when a registrant fails to provide pro forma disclosures under ASC 805-10-50 about the effects of an acquisition as of the beginning of a reporting period. ASC 805-10-50-2(h)(3) states that the disclosure requirements for comparative financial statements are as follows:

[F]or a calendar year-end entity, disclosures would be provided for a business combination that occurs in 20X2, as if it occurred on January 1, 20X1. Such disclosures would not be revised if 20X2 is presented for comparative purposes with the 20X3 financial statements (even if 20X2 is the earliest period presented).

In accordance with ASC 805-10-50, registrants must also disclose the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combinations that are recognized in the reported pro forma information.

If certain criteria are met (e.g., if a significant business combination has occurred or is probable), registrants may also be required to (1) comply with SEC Regulation S-X, Rule 3-05, and (2) provide pro forma financial information that complies with SEC Regulation S-X, Article 11, in a registration statement, proxy statement, or Form 8-K.

The SEC staff has also asked registrants:

- Whether an acquisition meets the definition of a business under ASC 805-10-20.
- To indicate which specific elements related to their use of the acquisition method of accounting are not yet complete and why they have not been finalized.
- To identify and disclose the income statement classification of acquisition-related costs they incurred (e.g., due diligence fees, legal fees).
- Whether individually immaterial acquisitions are collectively material, which would require them to disclose certain information.
- Whether a transaction is considered to be an acquisition of an entity under common control.

For more information about SEC comment letter themes that pertain to the life sciences industry, see Deloitte's [SEC Comment Letters — Including Industry Insights: What “Edgar” Told Us](#) (updated October 2015).

On the Horizon

Clarifying the Definition of a Business

On November 23, 2015, the FASB issued a [proposed ASU](#) that would clarify the definition of a business in ASC 805 and provide a framework that an entity can use to determine whether a set of activities and assets (collectively, a “set”) constitutes a business.

The FASB issued the proposed ASU in response to stakeholder feedback indicating that the definition of a business in ASC 805 is too broad and that too many transactions are qualifying as business combinations even though many of these transactions may more closely resemble asset acquisitions. Because the current definition has been interpreted broadly, it can be inefficient and costly to analyze transactions and entities may not be able to use “reasonable judgment.” The proposed amendments would make application of the guidance more consistent and cost-efficient.

The proposed ASU’s Basis for Conclusions indicates that the amendments would “narrow the definition of a business and provide a framework that gives entities a basis for making reasonable judgments about whether a transaction involves an asset or a business.” In addition, the proposal provides examples illustrating the application of the amendments to the determination of whether a set is a business.

Thinking It Through

Concerns about the definition of a business were among the primary issues raised in connection with the Financial Accounting Foundation’s (FAF’s) May 2013 post-implementation review (PIR) [report](#) on Statement 141(R) (codified in ASC 805).

Significance of the Proposal

An entity uses the definition of a business in ASC 805 in determining whether to account for a transaction as an asset acquisition or a business combination. This distinction is important because the accounting for an asset acquisition significantly differs from the accounting for a business combination, as described in [Determining Whether an Asset Group Constitutes a Business](#) above.

The FASB considered addressing the concern about the definition of a business more directly by attempting to reduce or eliminate differences between the accounting for business combinations and that for asset acquisitions. However, to respond to stakeholder concerns in a timely fashion, the FASB decided to begin this project by clarifying the definition of a business.

Thinking It Through

The definition of a business in ASC 805 also affects other aspects of accounting such as disposal transactions, determining reporting units, and the business scope exception in ASC 810. The proposed amendments would cause fewer sets of assets (and liabilities) to be identified as businesses.

Challenges Related to Applying the Current Definition of a Business

The definition of a business would remain unchanged under the proposed ASU. ASC 805 defines a business as:

An 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.

The current implementation guidance in ASC 805-10-55-4 states that a “business consists of inputs and processes applied to those inputs that have the ability to create outputs.” A business has three elements — inputs, processes, and outputs. All businesses have inputs and processes, and most have outputs, but outputs are not required for a set to be a business. Further, ASC 805-10-55-5 states that “all of the inputs or processes that the seller used” in operating the set do not need to be part of the transaction “if market participants are capable of acquiring the [set] and continuing to produce outputs, for example, by integrating the [acquired set] with their own inputs and processes.”

Since the current implementation guidance does not specify the minimum inputs and processes required for a set to meet the definition of a business, some have interpreted the definition of a business broadly. Some have said that a set may qualify as a business even if no processes are acquired when revenue-generating activities continue after an acquisition or

if a market participant would be capable of integrating the acquired set with its own processes. For example, some believe that the acquisition of real estate with an in-place lease meets the definition of a business because a market participant is capable of acquiring an input (a building with a lease) and combining it with the market participant's own processes (processes to collect rent and maintain the building) to continue generating outputs (rental income). Others have said that the presence of any process can give rise to a business, regardless of the significance of that process.

In addition, ASC 805-10-55-4(c) refers to an output as having "the **ability** to provide a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants" (emphasis added). Many transactions can provide a return in some form (e.g., the acquisition of a new machine might lower costs). Thus, the definition of outputs has further contributed to broad interpretations of the definition of a business.

Single or Similar Asset Threshold

The proposed ASU "would provide a practical way to determine when a [set] is not a business." That is, "when substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets," the set would not be considered a business. When this threshold is met, an entity would not need to evaluate the rest of the implementation guidance. The Basis for Conclusions of the proposed ASU notes that the assessment may be either qualitative or quantitative. In some cases, an entity may be able to qualitatively determine that all of the fair value of the acquisition would be assigned to a single asset or a group of similar assets. An entity may also be able to qualitatively determine that the fair value of the acquisition would be assigned to multiple dissimilar assets, in which case the threshold would not be met. In other cases, an entity may need to perform a quantitative assessment.

In addition, the FASB "decided that the threshold could be met if the fair value is concentrated in a group of similar identifiable assets" (e.g., when "an entity acquires, for example, multiple versions of substantially the same asset type instead of . . . one asset"). The Board further notes that although it intended "to make the analysis practical, the criteria are intended to weigh the need for practicality with the risk that too many items are grouped together to avoid being considered a business."

To avoid inappropriate groupings of assets, the proposed ASU would add ASC 805-10-55-9C. This paragraph indicates that an entity should not combine the following assets into a single asset (or consider them to be similar assets):

- a. Tangible and intangible assets (for example, real estate and in-place lease intangibles)
- b. Identifiable intangible assets in different major intangible asset classes (for example, customer-related intangibles, trademarks, and in-process research and development), except for groups of identifiable intangible assets that are recognized and measured as a single identifiable asset in accordance with [ASC 805] (for example, complementary intangible assets that have similar useful lives . . .)
- c. Financial and nonfinancial assets
- d. Different major classes of financial assets (for example, cash, accounts receivable, and marketable securities)
- e. Different major classes of tangible nonfinancial assets (for example, inventory, manufacturing equipment, and automobiles).

The following example (reproduced from the proposed ASU) illustrates how a life sciences entity would apply the proposed guidance discussed above:

Case B: Acquisition of a Drug Candidate

805-10-55-56 Pharma Co. purchases from Biotech a legal entity that contains the rights to a Phase 3 compound being developed to treat diabetes (the in-process research and development project). Included in the in-process research and development project [are] the historical know-how, formula protocols, designs, and procedures expected to be needed to complete the related phase of testing. The legal entity also holds an at-market clinical research organization contract and an at-market clinical manufacturing organization contract. The clinical research organization contract provides services in which the vendor performs certain research and development activities that are part of the current phase of the research and development activities required by the U.S. Food and Drug Administration. The clinical manufacturing organization contract provides access to some of the necessary materials to perform those activities. No employees, other assets, or other activities are transferred.

805-10-55-57 Pharma Co. first considers the guidance in [ASC] 805-10-55-9A [added by the proposed ASU] and analyzes whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. Pharma Co. concludes that the in-process research and development project is an identifiable intangible asset that would be accounted for as a single asset in a business combination. Pharma Co. also concludes that there is no fair value associated with the clinical research organization contract and the clinical manufacturing organization contract. Therefore, all of the consideration in the transaction would be allocated to the in-process research and development project. As such, [Pharma Co.] concludes that substantially all of the fair value of the gross assets acquired is concentrated in the single in-process research and development asset and the set is not a business.

Substantive Process

The proposed amendments would clarify that to be “a business, a transaction must include, at a minimum, an input and a **substantive** process” (emphasis added). Further, the Board points out that “the existence of a process (or processes) is what distinguishes a business from an asset because all asset acquisitions have inputs, and, therefore, providing additional guidance related to processes should help differentiate between [groups of] assets and businesses.”

The proposed amendments would not change the definition of a process, but they would add two different sets of criteria for entities to consider in determining whether a set has a substantive process; these criteria depend on whether a set has outputs.

A Set With No Outputs

When outputs are not present, an entity would need to apply more stringent criteria when determining whether a set has a substantive process (e.g., an early-stage company that has not generated revenues). The proposal points out that “[b]ecause outputs are a key element of a business and [because] a business usually has outputs, . . . when that key element is missing, the other elements should be more significant.” Therefore, to qualify as a business, a set that does not have outputs would need to have both an input and a substantive process. The set would include a substantive process “if it includes an organized workforce that has the necessary skills, knowledge, or experience to perform an acquired process (or group of processes) that, when applied to another acquired input or inputs, is critical to the ability to develop or convert that acquired input or inputs into outputs.” The existence of any employee does not mean that a set without outputs should be considered a business. The proposal notes that in the evaluation of whether an acquired workforce is performing a substantive process, the following factors should be considered:

- a. A process (or group of processes) is not critical if, for example, it is considered ancillary or minor in the context of all the processes required to create outputs.
- b. Inputs that the organized workforce could develop (or is developing) or convert into outputs could include the following:
 1. Intellectual property that could be used to develop a good or service
 2. Resources that could be developed to create outputs
 3. Access to necessary materials or rights that enable the creation of future outputs.

Examples could include technology, mineral interests, real estate, or in-process research and development.

The following example (reproduced from the proposed ASU) illustrates the assessment a life sciences entity would perform when a set has no outputs:

Case E: Acquisition of Biotech

805-10-55-67 Pharma Co. buys all of the outstanding shares of Target Biotech. Target Biotech’s operations include research and development activities on several preclinical compounds that it is developing (in-process research and development projects). The set includes the scientists that have the necessary skills, knowledge, or experience to perform research and development activities. In addition, Target Biotech has long-lived tangible assets such as a corporate headquarters, a research lab, and testing equipment. Target Biotech does not yet have a marketable product and, therefore, has not generated revenues.

[ASC 805-10-55-68 (added by the proposed ASU) omitted]

805-10-55-69 Because the set does not have outputs, Pharma Co. evaluates the criteria in [ASC] 805-10-55-5A [added by the proposed ASU] to determine whether the set has both an input and a substantive process. [Pharma Co.] concludes that the criteria in [ASC] 805-10-55-5A are met because the scientists make up an organized workforce that has the necessary skills, knowledge, or experience to perform processes that, when applied to the in-process research and development inputs, is critical to the ability to develop those inputs into a good that can be provided to a customer. The presence of a more than insignificant amount of goodwill is another indicator that the workforce is performing a critical process. Thus, the set includes both inputs and substantive processes and is a business.

A Set With Outputs

The Basis for Conclusions of the proposed ASU indicates that when a set has outputs (i.e., there is a continuation of revenues before and after the transaction), “it is more likely that the set includes both an input and a substantive process when compared with a set that is not generating outputs.” Therefore, the criteria for determining whether a set with outputs has a substantive process are less stringent. ASC 805-10-55-5B (added by the proposed ASU) indicates that the set would include a substantive process if any of the following criteria are met:

- a. An organized workforce that has the necessary skills, knowledge, or experience to perform an acquired process (or group of processes) that when applied to an acquired input or inputs, is critical to the ability to continue producing outputs. A process (or group of processes) is not critical if, for example, it is considered ancillary or minor in the context of all of the processes required to continue producing outputs.
- b. The acquired process (or group of processes), when applied to an acquired input or inputs, contributes to the ability to continue producing outputs and cannot be replaced without significant cost, effort, or delay in the ability to continue producing outputs.
- c. The acquired process (or group of processes), when applied to an acquired input or inputs, contributes to the ability to continue producing outputs and is considered unique or scarce.

An organized workforce may signify the existence of a substantive process but would not be required if outputs are present. The Basis for Conclusions of the proposed ASU states, for example, that “an organized workforce might not be required if the set includes automated processes (for example, through acquired technology, infrastructure, or specialized equipment) or other significant processes that contribute to the ability to continue producing outputs.”

Further, ASC 805-10-55-5C (added by the proposed ASU) states:

If a set has outputs, a continuation of revenues does not, on its own, indicate that both an input and a substantive process have been acquired. Accordingly, assumed contractual arrangements that provide for the continuation of revenues (for example, customer contracts, customer lists, and leases [when the set is the lessor]) should be excluded from the analysis . . . of whether a [substantive] process has been acquired.

The following example (reproduced from the proposed ASU) illustrates the application of the above proposed guidance to arrangements involving licensing and distribution rights, which are common among life sciences entities:

Case F: License of Distribution Rights

805-10-55-70 Company A is a global producer of food and beverages. Company A enters into an agreement to license the Latin American distribution rights of Yogurt Brand F to Company B whereby Company B will be the exclusive distributor of Yogurt Brand F in Latin America. As part of the agreement, Company A transfers the existing customer contracts in Latin America to Company B. Companies A and B also enter into an at-market supply contract in which Company B will purchase all of Yogurt Brand F from Company A. Company A retains all of its manufacturing and distribution capabilities. That is, Company B does not acquire manufacturing inputs and processes or distribution inputs and processes (and does not have any of the intellectual property related to those processes or to direct Company A’s processes in any way) but only will purchase finished goods from Company A that it will sell and distribute to end customers in Latin America.

[ASC 805-10-55-71 (added by the proposed ASU) omitted]

805-10-55-72 The set has outputs through the continuation of revenues with customers in Latin America. As such, Company B must evaluate the criteria in [ASC] 805-10-55-5B to determine whether the set includes an input and a substantive process that together contribute to the ability to create outputs. Because the customer contracts are excluded from the determination of whether a process is present in accordance with [ASC] 805-10-55-5C, the only elements in the set to evaluate to determine whether a substantive process is present are the license and supply agreement, both of which are inputs. That is, Company B did not obtain any process that could be applied to an acquired input to produce or distribute Yogurt Brand F but, rather, only a right to distribute and the access to purchase Yogurt Brand F. Because the set does not include an organized workforce and there are no acquired processes that could meet the criteria in [ASC] 805-10-55-5B(b) through (c), the set is not a business because it does not include both an input and a substantive process.

Definition of Outputs

The proposed amendments would change the definition of outputs to the “result of inputs and processes applied to those inputs that provide goods or services to customers, other revenues, or investment income, such as dividends or interest.” As explained in the proposed ASU’s Basis for Conclusions, the definition of outputs would be narrowed to be consistent with ASC 606, which “describes goods or services that are an output of the entity’s ordinary activities.” However, not every entity has revenues within the scope of ASC 606. Therefore, the Board decided to incorporate into the definition of outputs other types of revenues. For example, the reference to investment income in the definition of outputs in the proposed amendments was included to ensure that the purchase of an investment company could still qualify as a business combination.

Next Steps

Comments on the proposed ASU were due by January 22, 2016. An entity would apply the proposed amendments prospectively to any transaction that occurs on or after the effective date and would not be required to provide any disclosures at transition. The proposal notes that the FASB “will determine the effective date and whether the proposed amendments may be applied before the effective date after it considers stakeholder feedback on the proposed amendments.”

On February 17, 2016, the FASB made tentative decisions related to clarifying the scope of ASC 610-20 and accounting for partial sales of nonfinancial assets. The Board also made tentative decisions related to the accounting for undivided interests, the unit of account in partial sales transactions, and the transition method. For more information, see the FASB’s [summary](#) of the tentative Board decisions reached at the meeting.

Convergence With IFRSs

The definition of a business in ASC 805 is currently identical to that in IFRS 3. Nevertheless, the interpretation and application of this term in jurisdictions that apply U.S. GAAP do not appear consistent with those in jurisdictions that apply IFRSs (i.e., the definition of a business in IFRS jurisdictions is not applied as broadly). Although the proposed ASU would add implementation guidance to U.S. GAAP that is not found in IFRSs, the FASB intends to more closely align practice under U.S. GAAP with that under IFRSs by narrowing application of the U.S. GAAP definition. Further, the IASB has added a project on the definition of a business to its agenda and is considering making amendments similar to those in the proposed ASU.

Accounting for Goodwill for Public Business Entities and Not-for-Profit Entities

Background

In November 2013, the FASB endorsed a decision by the PCC to allow nonpublic business entities to amortize goodwill and perform a simplified impairment test. The Board received feedback on the PCC’s decision indicating that many public business entities and not-for-profit entities had similar concerns about the cost and complexity of the annual goodwill impairment test. In response, the Board added this project to its agenda in 2014.

Current Status and Next Steps

The project is currently in the initial deliberations phase. To date, the FASB has tentatively decided to split the project into two phases. The first phase would focus on simplifying the goodwill impairment test. In the second phase, the Board would work with the IASB to address stakeholder concerns related to the subsequent accounting for goodwill.

At the FASB's October 2015 meeting, the Board discussed how to simplify the goodwill impairment test and tentatively decided to remove step 2, thus eliminating the requirement to complete a hypothetical purchase-price allocation. The FASB also tentatively decided not to give entities the option to perform step 2 and to instead require them to adopt the simplified impairment test prospectively.

In addition, the Board discussed whether not-for-profit entities should be allowed to adopt PCC accounting alternatives. The FASB tentatively decided not to extend to not-for-profit entities the accounting alternative in ASU 2014-02, which allows private entities to amortize goodwill as well as complete only step 1 of the goodwill impairment test (at the entity or reporting-unit level) upon a triggering event.

At the FASB's January 2016 meeting, the Board decided that entities should apply the same impairment model for a reporting unit with a zero or negative carrying amount as the model for a reporting unit with a positive carrying amount by comparing the fair value of the reporting unit to its carrying amount. Further, the Board directed its staff to draft a proposed ASU for vote by written ballot, with a comment period of 60 days.

Accounting for Identifiable Intangible Assets in a Business Combination for Public Business Entities and Not-for-Profit Entities

Background

In November 2014, the FASB agreed to add a project to its agenda to explore potential changes to the existing model on accounting for identifiable intangible assets in a business combination for public business entities and not-for-profit entities. The Board will evaluate whether certain intangible assets should be subsumed into goodwill.

Current Status and Next Steps

The project is currently in the initial deliberations phase. At its October 28, 2015, meeting, the Board decided to continue further research in conjunction with the IASB's project on this topic.

Simplifying the Equity Method of Accounting

On June 5, 2015, the FASB issued a [proposed ASU](#) on equity method accounting as part of its simplification initiative. The proposal would eliminate the requirements for an investor to (1) account for basis differences related to its equity method investees and (2) retroactively account for an investment that becomes newly qualified for use of the equity method because of an increased ownership interest, as if the equity method had been applied during all previous periods in which the investment was held. Comments on the proposed ASU were due by August 4, 2015.

Thinking It Through

The comment letters to the FASB on the proposed ASU generally supported the Board's efforts to reduce the complexity related to the equity method of accounting. Most respondents approved of the Board's proposal to eliminate retrospective application of the equity method of accounting when an investment qualifies for the use of such accounting as a result of an increased level of ownership. However, concerns were raised that eliminating the requirement to account for basis differences related to an equity method investee could introduce new challenges when the investee has a single (or a predominant) asset.

At its November 2015 meeting, the Board affirmed the proposal to eliminate the requirement that entities retroactively account for an investment that becomes newly qualified for use of the equity method because of an increased ownership interest, as if the equity method had been applied during all previous periods in which the investment was held. Further, the Board directed its staff to research additional alternatives for improving the equity method of accounting.

For additional information about the proposed ASU, see Deloitte's June 16, 2015, [Heads Up](#) and August 4, 2015, [comment letter](#) to the FASB.

Proposed Changes to Effective Date and Transition Guidance in Certain Private-Company ASUs

On September 30, 2015, the FASB issued for public comment a [proposed ASU](#) that would give private companies a one-time unconditional option to forgo a preferability assessment the first time they elect a PCC accounting alternative within the proposal's scope. It would also eliminate the effective dates of PCC accounting alternatives that are within the proposal's scope as well as extend the transition guidance in [ASU 2014-02](#) and [ASU 2014-03](#). The proposal's amendments could affect all private companies within the scope of ASU 2014-02 and ASU 2014-03 as well as [ASU 2014-07](#) and [ASU 2014-18](#). See Deloitte's October 6, 2015, [Heads Up](#) for more information.



Consolidation

Introduction

Life sciences entities enter into a variety of arrangements with other parties to facilitate the research, development, or sale of their intellectual property or products. Because life sciences entities may absorb risk and rewards of other parties through interests other than those based on traditional voting equity, they must carefully analyze their arrangements with those parties to determine whether to consolidate them. The dual consolidation model, which comprises the variable interest entity (VIE) model and the voting interest entity model, is designed to ensure that the reporting entity that consolidates another legal entity has (1) the right and obligation to absorb the other legal entity's returns and losses and (2) the power to direct the activities that most significantly affect the other legal entity.

After more than four decades of little change, the accounting guidance on consolidation has been evolving rapidly over the past 15 years. [ASU 2015-02](#) is the latest chapter in the consolidation evolution story. While the ASU did not introduce any new models, its changes eliminated two of the existing models (FIN 46(R) and EITF Issue 04-5), requiring all entities to be evaluated as either a voting interest entity or a VIE. Further, under the ASU, the evaluation of whether a VIE should be consolidated is still based on whether the reporting entity has both (1) power and (2) potentially significant economics.

Some key highlights of the ASU's changes are as follows:

- The Statement 167 deferral for interests in investment companies (and certain similar entities) has been eliminated, thereby removing the risks-and-rewards-based consolidation model under FIN 46(R) from U.S. GAAP.
- The limited partnership model in ASC 810-20 has been eliminated. Instead, limited partnerships will be VIEs unless the limited partners have substantive kick-out or participating rights. Although more limited partnerships will be VIEs, it is less likely that a general partner will consolidate a limited partnership.
- The guidance on fees paid to a decision maker or service provider has been amended. Specifically, it is less likely that the fees themselves would be considered a variable interest, that a legal entity would be a VIE, or that a decision maker would consolidate the legal entity.
- The ASU significantly amends how variable interests held by a reporting entity's related parties or de facto agents affect its consolidation conclusion. In addition, the ASU will result in less frequent performance of the related-party tiebreaker test (and mandatory consolidation by one of the related parties) than under the previous VIE models.

ASC 810-10-05-6 contains a flowchart that consists of a series of decision trees to help reporting entities identify (1) which consolidation model to apply, if any; (2) whether a reporting entity should consolidate a VIE; and (3) whether a reporting entity should consolidate a voting interest entity. See Deloitte's [Consolidation — A Roadmap to Identifying a Controlling Financial Interest](#) for a flowchart that incorporates the concepts in the FASB's flowchart and serves as a guide to the consolidation accounting literature.

ASU 2015-02 affects all entities with variable interests in other entities. Reporting entities must document their considerations of the new guidance and how it affects any previous consolidation conclusions or their identification of other legal entities as VIEs. For public business entities, the guidance in ASU 2015-02 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. For entities other than public business entities, the guidance is effective for annual periods beginning after December 15, 2016, and interim periods beginning after December 15, 2017. Early adoption is allowed for all entities (including during an interim period), but the guidance must be applied as of the beginning of the annual period containing the adoption date. A reporting entity may apply the ASU's amendments by using a full retrospective or a modified retrospective approach. Under a full retrospective approach, the reporting entity would retrospectively apply the ASU to one or more years presented in its financial statements and record a cumulative-effect adjustment to retained earnings as of the beginning of the first year presented. Under a modified retrospective approach, the reporting entity would record a cumulative-effect adjustment to equity as of the beginning of the period of adoption. In selecting a transition option, a reporting entity should consider, among other factors, the effort required to recast previous periods and the impact on the financial statements presented.

Featured Interpretive Guidance

The discussions and examples below contain guidance on consolidation matters that frequently affect life sciences entities or are expected to affect life sciences entities upon adoption of ASU 2015-02. The guidance cited is not intended to be all-inclusive or comprehensive; rather, it provides targeted considerations related to the application of the standard that are most relevant to the industry. To complete a consolidation analysis, entities must consider all facts and circumstances and use significant judgment. The examples cited will be beneficial in introducing concepts as you approach any newly acquired variable interests or perform reassessments under the new standard's amendments to existing guidance.

Scope Exceptions to the Consolidation Guidance — Business Scope Exception

After the identification of a potential variable interest in a legal entity, a reporting entity should evaluate whether it can apply the scope exceptions to the VIE model. The most frequently cited exception is the so-called business scope exception. (For a list of all consolidation and VIE scope exceptions, see Section 3 of Deloitte's *Consolidation — A Roadmap to Identifying a Controlling Financial Interest*.)

The business scope exception is two-pronged and premised on both (1) the legal entity's characteristics (i.e., whether it is a business as defined in ASC 805) and (2) the reporting entity's relationship with the legal entity (e.g., the extent of involvement by the reporting entity in the design or redesign of the legal entity, whether the legal entity is designed so that substantially all of its activities either involve or are conducted on behalf of the reporting entity and its related parties, and whether the reporting entity and its related parties provided more than half of the subordinated financial support.) A common oversight in evaluating the applicability of the business scope exception is merely assessing whether a legal entity meets the definition of a business and failing to determine whether any of these conditions is met. Two of the more common relationships that must be analyzed are described below.

Substantially All of the Activities Either Involve or Are Conducted on Behalf of the Reporting Entity

A reporting entity should base its determination of whether substantially all of a legal entity's activities either involve or are conducted on behalf of the reporting entity and its related parties on the design of the legal entity and should compare the nature and extent of the activities between the reporting entity and the legal entity with the entire set of the legal entity's activities.

Example

A joint venture entity (Entity P) is formed by two unrelated parties, Enterprises U and G. Each investor has a 50 percent equity interest. Entity P's activities consist solely of developing pharmaceutical products, and the reporting entity, U, has the rights to the resulting products. As currently designed, P represents a development arm of U's business because it is so closely aligned with U in appearance and purpose. Therefore, substantially all of P's activities either involve or are conducted on U's behalf and, accordingly, the business scope exception cannot be applied by U.

Additional Subordinated Financial Support — Put and Call Options

Put and call options may exist in agreements between equity owners in a life sciences legal entity (e.g., between joint venture partners). Such options can have an impact on whether a reporting entity meets the condition in ASC 810-10-15-17(d)(3) and, therefore, on whether the reporting entity can apply the business scope exception. The following examples illustrate situations in which (1) a put option (purchased by one investor from the reporting entity) results in the reporting

entity’s ineligibility for the business scope exception since the reporting entity effectively provides more than half of the total equity, subordinated debt, and other forms of subordinated financial support to the legal entity and (2) a call option would not have the same impact:

Example — Put Option

Investor A and Investor B form Entity X with equal contributions of equity. Investor B purchases a put option from A that permits it to put its interest in X to A at a fixed price.

The fair value of the fixed-price put option should be considered additional subordinated financial support provided by A to X because A will absorb expected losses of X upon exercise of that put option (i.e., it meets the definition of subordinated financial support in ASC 810-10-20). Therefore, A would consider the fair value of the fixed-price put option (presumably the price paid) in determining whether the condition in ASC 810-10-15-17(d)(3) is met. If the fair value of the put option is greater than zero, A would meet this condition and therefore would not be able to use the business scope exception since the fair value of the equity provided by A and the fair value of the put option written by A would constitute more than half the total of the equity, subordinated debt, and other forms of subordinated financial support to the legal entity.

Example — Call Option

Investor A and Investor B form Entity X with equal contributions of equity. Investor A purchases a call option from B that permits it to call B’s interest at a fixed price (the call option’s strike price is at or above the fair value of the equity interest at inception of the option).

The fair value of the fixed-price call option should not be considered additional subordinated financial support to X because A will not absorb expected losses of X upon exercise of that call option (i.e., the option does not meet the definition of subordinated financial support in ASC 810-10-20). Investor A can exercise its call and obtain additional residual returns of X, but the call option does not expose it to additional expected losses. Therefore, A would not consider the fair value of the fixed-price call option in determining whether it meets the condition in ASC 810-10-15-17(d)(3). Investors A and B would not meet this condition since the fair value of the equity provided by each investor would not constitute more than half of the total of the equity, subordinated debt, and other forms of subordinated financial support to the legal entity. To use the business scope exception, A and B must determine whether the other conditions in ASC 810-10-15-17(d) are met.

Identifying Variable Interests

One of the first steps in assessing whether a reporting entity is required to consolidate another legal entity is to determine whether a reporting entity holds a variable interest in the legal entity being evaluated for consolidation. If a reporting entity does not have a variable interest in the legal entity, no further analysis is required. That is, that reporting entity is not required to consolidate the legal entity or provide any of the VIE disclosures related to the legal entity. While there are many forms of variable interests, all variable interests will **absorb** portions of an entity’s variability (changes in the fair value of the entity’s net assets) that the legal entity was designed to create. An interest that **creates** variability would not be considered a variable interest.

The FASB established a two-step “by-design” approach for the identification of variable interests. Under this approach (ASC 810-10-25-22), the reporting entity would (1) “[a]nalyze the nature of the risks in the legal entity” and (2) “[d]etermine the purpose(s) for which the legal entity was created and determine the variability (created by the risks identified in Step 1) the legal entity is designed to create and pass along to its interest holders.” ASC 810-10-20 defines variable interests in a VIE as “contractual, ownership, or other pecuniary interests in a VIE that change with changes in the fair value of the VIE’s net assets exclusive of variable interests.”

It is often simple to determine whether an arrangement is a variable interest. A good rule of thumb is that most arrangements on the credit side of the balance sheet (e.g., equity and debt) are variable interests because they absorb variability as a result of the performance of the legal entity. However, determining whether other arrangements (e.g., derivatives, leases, and decision-maker and other service-provider contracts) are variable interests can be more complex. The table below contains a very limited list of examples of what may be considered variable interests:

Types of Variable Interests	Illustrative Examples
Long-term liabilities of a legal entity (e.g., fixed-rate debt, floating-rate debt, mandatorily redeemable preferred stock)	Aspen Co. (the reporting entity) lends Dunne Co., a biotech firm, \$50 million in the form of a five-year fixed-rate unsecured loan. Aspen Co., as a debt holder, absorbs the variability in the value of the legal entity’s assets because Aspen Co. is exposed to Dunne Co.’s ability to pay (i.e., credit risk) and may also be exposed to interest rate risk depending on the design of the legal entity.
Equity of a legal entity (e.g., mezzanine equity, preferred stock, common stock, partnership capital)	Schrute LP (the reporting entity) invests \$89 million in Michael Co., a contract research organization. The equity investment was made in common stock and is considered equity at-risk under ASC 810-10-15-14(a). Schrute LP’s interest in Michael Co. is a variable interest that absorbs the variability associated with changes in Michael Co.’s net assets.
Guarantees written by a reporting entity	Costanza Inc. (the reporting entity) provides a guarantee to a medical device company, Ball Investments Inc., on the \$2 billion fair value of all medical device intellectual property held by Ball Investments Inc. Costanza Inc. must pay Ball Investments Inc. for any decreases in value of this intellectual property. The guarantee agreement transfers all or a portion of the risk of specified assets (intellectual property); thus, Costanza Inc. has a variable interest in Ball Investments Inc.
Put options written by a reporting entity and similar arrangements on specified assets owned by the legal entity*	Hermanos LLC (the reporting entity) writes a put option to White Inc. allowing White Inc. to sell its medicinal compound in development for a fixed price at a later date. Hermanos LLC has a variable interest in the specified assets of White Inc.
Stand-alone call options written by the legal entity on specified assets owned by that legal entity*	Sterling Inc. writes a call option on its wholly owned interest in a treatment in phase II clinical trials to Draper LP (the reporting entity), allowing Draper LP to acquire the interest for a fixed price at a later date. Because Draper LP participates in the positive variability of the specified assets of Sterling Inc., Draper LP possesses a variable interest in those specified assets.
Fees paid to a decision maker or service provider	Snow LLC pays a fee to Red Corp. (the reporting entity) to distribute Snow LLC’s products. The fee arrangement requires Snow LLC to pay Red Corp. all profits earned on the distribution of the products. In accordance with ASC 810-10-55-37C, the fee arrangement is designed to transfer substantially all of the residual returns and risks of ownership of Snow LLC’s products to Red Corp., the decision maker. Red Corp.’s earned fee represents a variable interest in Snow LLC.
Royalties and licenses paid to a reporting entity	Caspian Inc. (the reporting entity) holds rights to a pharmaceutical drug. Wilson Inc. obtains a license from Caspian Inc. to produce, market, and sell the drug, and Caspian Inc. will earn a royalty based on Wilson Inc.’s sales. Caspian Inc. holds a variable interest in Wilson Inc. because it absorbs variability through the royalty.

* ASC 810-10-25-55 and 25-56 indicate that variable interests in a specified asset whose value is less than half of the total fair value of a VIE’s assets are not considered variable interests in that legal entity unless the reporting entity also holds another interest in the legal entity. In addition, the variable interest could result in consolidation of a “silo” within a VIE. See Sections 4.3.11 and 6 of *Consolidation — A Roadmap to Identifying a Controlling Financial Interest* for further discussion.

The table below lists examples of what generally would not be considered variable interests:

Types of Nonvariable Interests	Illustrative Examples
Assets of the legal entity	David Inc. (the reporting entity) owes \$100 million to Prettay LP as part of an existing loan agreement. Although the loan receivable asset generates value to the investors of Prettay LP, the loan receivable is not a variable interest to David Inc. Assets of a legal entity typically are the major source of a legal entity's variability, not an absorber of variability, and are therefore not considered variable interests.
Contingent payments made to a legal entity	Ernie Pharmaceuticals Inc. (the reporting entity) enters into an agreement with Clementine LLC to continue the R&D of a phase I drug held by Clementine LLC. In exchange for the drug's achievement of milestones, such as FDA approval and the achievement of specified sales levels, Ernie Pharmaceuticals Inc. will make milestone payments and pay Clementine LLC royalties. Ernie Pharmaceuticals Inc. is not exposed to the variability in Clementine LLC and therefore does not possess a variable interest through its milestone or royalty payments.

Discussion of the by-design approach for identifying variable interests, along with a more expansive list of illustrative examples of variable interests, is included in Section 4 of Deloitte's [Consolidation — A Roadmap to Identifying a Controlling Financial Interest](#).

Determining Whether a Legal Entity Is a VIE

To determine which consolidation model to apply when evaluating its variable interest in a legal entity, a reporting entity must determine whether the legal entity is a VIE. This determination must be made upon the reporting entity's initial involvement with the legal entity and reassessed upon the occurrence of a reconsideration event.

Legal entities can differ in structure as well as legal form (e.g., corporations compared with limited partnerships and similar entities), which affects the method used to understand their design and purpose. In simple terms, the distinction is based on the nature and amount of the equity investment and the rights and obligations of the equity investors.

To qualify as a VIE, a legal entity needs to satisfy only one of the following characteristics:

- The legal entity does not have sufficient equity investment at risk.
- The equity investors at risk, as a group, lack the characteristics of a controlling financial interest.
- The legal entity is structured with disproportionate voting rights, and substantially all of the activities are conducted on behalf of an investor with disproportionately few voting rights.

Below is a brief list of considerations specifically relevant to life sciences entities for determining whether the legal entity is a VIE. Since this list is not all-encompassing, we encourage you to refer to Section 5 of Deloitte's [Consolidation — A Roadmap to Identifying a Controlling Financial Interest](#) during your analysis.

The Legal Entity Does Not Have Sufficient Equity Investment at Risk

If a legal entity has sufficient equity investment at risk to finance its operations, and the equity investors make decisions that direct the significant activities of the legal entity, consolidation based on majority voting interest is generally appropriate. However, if equity is not sufficient, or the equity investors do not control the legal entity through their equity investment, the VIE model is used to identify the appropriate party, if any, to consolidate.

Determining Whether the Equity Investment Is "At Risk"

An interest classified as equity may not have the substantive characteristics of equity. Since the VIE consolidation framework is intended to apply to entities whose voting interests may not be the most appropriate determining factor, the FASB reasoned that equity interests that are not "at risk" should not be included in the sufficiency-of-equity test. To be considered part of the equity investment at risk, equity interests must (1) participate significantly in profits and losses, (2) not be issued

in exchange for subordinated interests in other VIEs, (3) not be received from the legal entity or by parties involved with the legal entity (see example below), and (4) not be financed by the legal entity or other parties involved with the legal entity. Further, equity investments acquired by an equity investor in exchange for promising to perform services cannot be considered equity investment at risk, because the equity is received in lieu of a fee for services performed. Similarly, equity investments acquired as a result of past services performed are not considered equity investment at risk.

Example

Three investors form Entity X to conduct R&D activities. Entity X issues equity with a par amount of \$15 million (\$5 million to each investor). Investor A contributes \$5 million in cash. Investor B issues a guarantee that the fair value of the compound at the completion of the R&D activities will be at least \$90 million. Investor C enters into an agreement with X to provide research scientists who will work for 500 hours to complete the activities.

Only A's \$5 million in equity is considered equity at risk because B and C received their equity as payment from X for the guarantee (promise to stand ready) and the performance of services, respectively.

Determining Whether the Identified Equity Investment at Risk Is Sufficient to Finance the Legal Entity's Operations Without Additional Subordinated Financial Support

Once the amount of equity investment at risk is quantified, a reporting entity must determine whether the equity investment at risk is sufficient to finance the legal entity's operations without additional subordinated financial support. If not, the legal entity is a VIE. The purpose of this assessment is to identify whether a legal entity is sufficiently capitalized. Merely having at-risk equity is not enough; the legal entity must be able to finance its operations with the equity investment at risk. The reporting entity must use judgment to determine sufficiency since the various risk tolerances, investment objectives, and liquidity requirements of investing can influence the level of capital in a legal entity.

Existence of Subordinated Debt

In evaluating whether equity investment at risk is sufficient, consideration should also be given to whether the entity has outstanding, or could issue, investment-grade debt since such debt is typically issued only when third parties deem a legal entity to be sufficiently capitalized. If debt is subordinated to other variable interests, equity investment at risk may be insufficient to finance the legal entity's operations. The determination of whether debt represents subordinated financial support is based on how that debt absorbs expected losses compared with other variable interests in the legal entity. If the terms of the debt arrangement cause the debt to absorb expected losses before or at the same level as the most subordinated interests (e.g., equity, other subordinated debt), or the most subordinated interests are not large enough to absorb the legal entity's expected losses, the debt would generally be considered subordinated financial support. However, investment-grade debt is a variable interest that would generally not be considered subordinated financial support because investment-grade debt generally indicates that third parties deem the legal entity to be sufficiently capitalized. Consider the following example:

Example

Entity D is formed with \$50 of equity and \$50 of long-term debt. The long-term debt consists of two issuances: (1) Debt A, \$45; and (2) Debt B, \$5. Debt B is subordinate to Debt A. Because D was recently formed, it could not obtain senior debt (Debt A) in an investment-grade form.

In a qualitative assessment, the existence of subordinated debt is a factor indicating that D does not have sufficient equity at risk. That factor should be considered along with all other facts and circumstances (e.g., a 50 percent ratio of equity at risk frequently exceeds expected losses). If the qualitative assessment is inconclusive, a quantitative analysis (i.e., calculation of expected losses/residual returns) should be performed to determine whether D is a VIE.

Example (continued)

Assume that D was a VIE at formation. Two years after its formation, D engages in additional business activities beyond those that were considered at formation and is an established, profitable business. Given its desire to further expand its business, D issues a new tranche of debt (Debt C) whose rank is identical in seniority (e.g., priority in liquidation) to that of Debt B. Because of its stable financial condition, the tranche of debt is rated investment-grade. Given the identical priority in liquidation of Debt B and Debt C, one can infer that Debt A (which is senior to Debt B) and Debt B would be rated investment-grade as well. No other debt securities are outstanding, and no other evidence of subordinated financial support (e.g., guarantees) is noted. Assume that a reconsideration event under ASC 810-10-35-4(c) has occurred because the additional business activities increase D's expected losses. Therefore, the variable interest holders must determine whether D is still a VIE.

In a qualitative assessment, D's ability to issue investment-grade debt that has the same priority in liquidation as Debt A and Debt B is one factor indicating that D, as of the reconsideration date, has sufficient equity at risk. That is, in the absence of other forms of subordinated financial support, D would not have been able to obtain an investment-grade rating on the new debt if its existing equity at risk was not sufficient. However, all other facts and circumstances existing as of the reconsideration date should be considered. If the qualitative assessment is not conclusive, a quantitative analysis should be performed to determine whether D is a VIE as of the reconsideration date.

Development-Stage Entities

Life sciences entities frequently require varying levels of funding to complete a product candidate's R&D; understanding "the sufficiency of the equity at risk" to fund each phase of R&D is therefore important to the VIE analysis.

Recognizing the unique funding needs of early-stage entities, the FASB had provided a different framework for evaluating the sufficiency of equity investment at risk for all development-stage entities. ASC 915-10-20 defines a development-stage entity as follows:

An entity devoting substantially all of its efforts to establishing a new business and for which either of the following conditions exists:

- a. Planned principal operations have not commenced.
- b. Planned principal operations have commenced, but there has been no significant revenue therefrom.

Before the adoption of [ASU 2014-10](#),¹ the following two conditions needed to be present for equity investment at risk to be considered sufficient for a development-stage entity:

- The legal entity must have had sufficient equity to fund its current developmental activity.
- The legal entity must have been legally structured to permit additional equity investment in the future, to fund further development upon completion of the current activity.

This framework was more generous than the approach applicable to entities that did not qualify as development-stage entities since it took into account the life cycle of the legal entity in phases rather than over the entire contemplated life of the legal entity. Under this framework, a reporting entity (1) initially assessed whether a development-stage entity was a VIE on the date the reporting entity first became involved with the legal entity and (2) reconsidered its assessment upon the occurrence of any of the events described in ASC 810-10-35-4. For a development-stage entity, such events would have included, but would not have been limited to:

- Funding of additional equity.
- Commencement of additional activities (e.g., entering a subsequent "phase" of development).

Although the concept of a development-stage entity has been removed in ASU 2014-10, we believe that it is still necessary to consider the design of a legal entity in the determination of whether its equity investment at risk is sufficient. That is, for certain legal entities that met the definition of a development-stage entity under previous guidance, considering only

¹ ASU 2014-10 eliminates the specialized approach for considering sufficiency of equity investment at risk for development-stage entities. That guidance is effective for public business entities for annual periods beginning after December 15, 2015, and interim periods therein. For entities other than public business entities, the guidance is effective for annual periods beginning after December 15, 2016, and for interim periods beginning after December 15, 2017. Early adoption is permitted. Reporting entities that have historically applied this exception should consider the impact of ASU 2014-10 on their historical conclusions.

the legal entity's current stage of development may be appropriate in the assessment of sufficiency of equity. Specifically, if a legal entity is in the development stage and there is substantial uncertainty about whether the legal entity will proceed to the next stage, it may be appropriate to consider only the current stage in the sufficiency assessment. This approach is consistent with the assessment of power in the primary beneficiary analysis of a multiple-stage entity.

Example

Entity D is a development-stage entity as previously defined in ASC 915. Investor A and Investor B each contributed \$1 million of equity financing to D. Entity D's current activities consist of early-stage (phase I) drug development. Upon successful completion of phase I, D plans to commence phase II trials. During the final phase of D's R&D stage, it plans to engage in phase III trials. Entity D's by-laws allow A and B to fund additional equity upon the completion of phase I and phase II. Given the low probability of technical and regulatory success of the drug being studied, there is substantial uncertainty about whether D will proceed to phase II of development.

When assessing the sufficiency of equity at risk under ASC 810-10-15-14(a), D need only consider the current phase of its development. Thus, if, at inception the \$2 million of equity capital is deemed sufficient to finance phase I, D would be considered to have sufficient equity investment at risk. This determination should be reassessed at the commencement of phase II and phase III, upon the funding of additional equity financing, or upon the occurrence of any of the events described in ASC 810-10-35-4.

Equity Investors, as a Group, Lack the Characteristics of a Controlling Financial Interest

A reporting entity determines whether it holds a controlling financial interest in a legal entity differently under the VIE model than it does under the voting interest entity model. The voting interest entity model focuses on the voting rights conveyed by equity interests. Since the holder of an interest other than equity may control the legal entity, the voting interest entity model may not yield an appropriate consolidation conclusion if the equity interests collectively do not possess the characteristics that are typical of equity interests. Accordingly, a legal entity is considered a VIE if any of the following three qualities — the "typical" characteristics of an equity investment — are absent from the holders of equity investment at risk **as a group**:

- The power to direct the most significant activities of the legal entity.
- The obligation to absorb the expected losses of the legal entity.
- The right to receive the expected residual returns of the legal entity.

The right of the equity investor group must be a characteristic of the equity interest itself and not a characteristic of other interests held by the current holders of the equity interests. Each individual equity investment at risk need not possess all three characteristics, but the total equity investment at risk must possess them all. By implication, as long as the group of equity investors possesses these three characteristics, the failure of any one at-risk equity investor to possess the characteristics would not make the legal entity a VIE.

Example

Stabler Inc. is the sole equity holder in an entity that holds the patent to a phase II drug. The phase II drug represents 80 percent of the fair value of the net assets held by Stabler Inc. To Benson LLC, Stabler Inc. issues a fixed-price call option on the phase II drug that is exercisable in one year. The right of Stabler Inc. to receive the expected residual returns is effectively capped because of Benson LLC's ability to participate in the upside through its call option. Consequently, Stabler Inc. is a VIE.

Disproportionate (Nonsubstantive) Voting Rights

Although intended to clarify the previous criteria (equity investors as a group do not possess characteristics of a controlling financial interest), the evaluation of whether disproportionate (nonsubstantive) voting rights exist is generally considered a separate condition in the assessment of a VIE. ASC 810-10-15-14(c)(2) explains that the provision "is necessary to prevent a primary beneficiary from avoiding consolidation of a VIE by organizing the legal entity with nonsubstantive voting interests." Thus, ASC 810-10-15-14(c) is referred to as the "anti-abuse provision" since it aims to prevent a legal entity from being

structured in a manner such that the legal entity does not confer voting control to a reporting entity but in substance should be consolidated by the reporting entity because “substantially all” of the legal entity’s activities either involve the reporting entity or are conducted on the reporting entity’s behalf. See Section 5.4 of Deloitte’s *Consolidation — A Roadmap to Identifying a Controlling Financial Interest* for more interpretive guidance on evaluating this criterion.

Identifying the Primary Beneficiary of a VIE

The primary beneficiary of a VIE is the party required to consolidate the VIE (i.e., the party with a controlling financial interest in the VIE). Upon the adoption of ASU 2015-02, the analysis for identifying the primary beneficiary is consistent for all VIEs. Specifically, ASC 810-10-25-38A requires the reporting entity to perform a qualitative assessment that focuses on whether the reporting entity has both “power” and “economics.” These two concepts are discussed below. For more detailed information, see Section 7 of Deloitte’s *Consolidation — A Roadmap to Identifying a Controlling Financial Interest*.

Power Criterion

Although identification of the primary beneficiary requires an evaluation of both characteristics of a controlling financial interest in a VIE, the determination is often based on which variable interest holder satisfies the power criterion since generally more than one variable interest holder meets the economics criterion.

To determine whether it meets the power criterion, the reporting entity must identify the activities that most significantly affect the VIE’s economic performance and then determine which variable interest holder has the power to direct those activities. The reporting entity would take the following steps to identify the party with the power to direct the activities that most significantly affect the VIE’s economic performance:

- *Step 1* — Evaluate the purpose and design of the VIE and the risks the VIE was designed to create and pass along to its variable interest holders.
- *Step 2* — Identify the significant decisions related to the risks identified in step 1 and the activities associated with those risks. In certain situations in which multiple unrelated variable interest holders direct different decisions and activities, the reporting entity must determine which activity most significantly affects the VIE’s economic performance. The party that has the power to direct such activity will meet the power criterion. When making this determination, the reporting entity should consider the activity that results in the most economic variability for the VIE (e.g., expected losses and expected residual returns).
- *Step 3* — Identify the party that makes the significant decisions or controls the activity or activities that most significantly affect the VIE’s economic performance. Consider whether any other parties have involvement in those decisions (shared power) or can remove the decision maker (kick-out rights).

While a VIE often performs a variety of activities, the key to determining whether the power criterion has been satisfied is identifying the activities that are most significant to the VIE’s economic performance.

Contingencies

Future power can be converted to a variable interest holder upon the occurrence of a contingent event. Questions have arisen about whether such a variable interest holder can be the primary beneficiary of the VIE before the occurrence of that contingent event. When a party can direct activities only upon the occurrence of a contingent event, the determination of which party has power will require an assessment of whether the contingent event results in a **change in power** (i.e., power shifts from one party to another upon other occurrence of a contingent event) over the most significant activities of the VIE (in addition, the contingent event may change what the most significant activities of the VIE are) or whether the contingent event **initiates** the most significant activities of the VIE (i.e., the VIE’s most significant activities only occur when the contingent event happens).

Example

Entity X is formed by two investors (A and B) to develop and manufacture a new drug. Assume that X is a VIE and that each investor holds a variable interest in X. Investor A has power over the R&D activities to develop and obtain FDA approval for the drug (stage 1), and those activities most significantly affect X's economic performance during that stage. Investor B has the power over the manufacturing process, distribution, and marketing of the drug (as well as protecting its patented formula) if and when FDA approval is obtained (stage 2), and those activities would most significantly affect X's economic performance during that stage. In determining which investor has the power to direct the activities that most significantly affect the economic performance of X, each investor should assess whether the contingent event (FDA approval) results in a change in power over the most significant activities of X (in addition, the contingent event may change what the most significant activities of X are) or whether the contingent event initiates the most significant activities of X.

Entity X was designed such that there are two distinct stages during its life, and the variable interest holders expect that the second stage will only begin upon FDA approval. Also, the activities and decisions before and after FDA approval are significant to the economic performance of X (in this example, they are different activities directed by different parties). In addition, the variable interest holders conclude that there is substantial uncertainty about whether FDA approval will be obtained and that the approval is outside their control. For these reasons, in the absence of evidence to the contrary, FDA approval would be considered a substantive contingent event that results in a change in power from A to B. Therefore the primary-beneficiary determination should focus on stage 1 activities until the contingent event occurs, and A (the investor that has the power over the R&D activities) would initially have the power to direct the most significant activities of X. If FDA approval is obtained, the primary-beneficiary determination would focus on stage 2 activities, and B (the variable interest holder that has the power over the manufacturing process, distribution, and marketing of the drug) would have the power to direct the most significant activities of X.

Economics Criterion

To satisfy the economics criterion in the analysis of the primary beneficiary of a VIE, the variable interest holder must have the obligation to absorb losses of the VIE that could potentially be significant to the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE. Said simply, the variable interest holder must have an exposure to the economics of the VIE that is more than insignificant. As a general guideline, the economics criterion would be met if the losses or returns that could potentially be absorbed through the reporting entity's variable interests in the VIE exceed, either individually or in the aggregate, 10 percent of the losses or returns of the VIE under any scenario. However, 10 percent should not be viewed as a bright line or safe harbor. That is, as a result of facts and circumstances, a reporting entity may conclude that the economics condition is met even if the losses or returns absorbed by the reporting entity's interests in the VIE are less than 10 percent. Because the threshold for meeting the economics criterion is low, most of the primary beneficiary analysis is focused on assessing the reporting entity's power over the significant activities that affect the VIE's performance.

Other Considerations

Because this publication is intended to highlight some of the complex issues frequently encountered by life sciences entities, certain consolidation topics are outside its scope. However, such topics are discussed in Deloitte's *Consolidation — A Roadmap to Identifying a Controlling Financial Interest*; they include (1) the assessment of related parties in the identification of variable interests and performance of primary beneficiary analyses, (2) consolidation evaluations involving voting interest entities, and (3) special considerations for limited partnerships and similar entities. For a summary of the key changes to ASC 810 as a result of ASU 2015-02, see Appendix A of the Consolidation Roadmap.

Further, for additional discussion of R&D funding arrangements that involve legal entities, refer to the [Revenue Recognition](#) section above.

SEC Staff Insights and Comment Letter Themes

SEC Staff Insights

As discussed in Deloitte's December 15, 2015, *Heads Up*, the 2015 AICPA Conference on Current SEC and PCAOB Developments featured insights on current accounting, reporting, and auditing practice topics, including consolidation. One consolidation issue addressed at the conference, which is relevant to certain life sciences entities, involves SEC registrants' foreign subsidiaries operating in jurisdictions with foreign currency exchange or government restrictions, particularly when those restrictions are so severe that they cast doubt on registrants' ability to control the foreign subsidiaries.

Specifically, Chris Semesky, professional accounting fellow in the SEC's Office of the Chief Accountant, discussed the lack of currency exchangeability in, and other government restrictions related to, registrants' foreign operations in Venezuela. In commenting on these situations, Mr. Semesky noted that deconsolidation of a foreign subsidiary may be appropriate if the foreign exchange or government restrictions are so severe that the registrant lacks control of the subsidiary. He indicated, however, that if the equity investors have lost control of the subsidiary, the registrant should carefully consider whether the foreign subsidiary is a VIE, emphasizing that in such circumstances, the registrant would need to consider ongoing disclosure of its variable interests, if any, in the foreign VIE in accordance with the disclosure requirements of ASC 810. In addition, Mr. Semesky cautioned that the registrant would need to have internal controls to monitor changes in the facts and circumstances of the foreign exchange restrictions and government-imposed controls to determine whether it has regained control of, and thus should reconsolidate, the foreign subsidiary.

SEC Comment Letter Themes

Examples of SEC Comments

- Please provide us with your detailed analysis of the accounting model and the authoritative accounting guidance you considered in your conclusion to consolidate [the legal entity]. Tell us whether [the legal entity] is subject to the consolidation guidance related variable interest entities and what consideration was given to the guidance in ASC 810-10-15-14(b)(1). If it is subject to this guidance, explain how you determined that you have the characteristics of a controlling financial interest per ASC 810-10-25-38A.
- You disclosed that at December 31, 2013, you consolidated an investment in [an] LLC where you were determined to be the primary beneficiary due to a related party affiliation. At June 30, 2014 you were no longer considered the primary beneficiary of this LLC and therefore deconsolidated this LLC in accordance with ASC 810. Please tell us how you determined that it was appropriate to deconsolidate this LLC. Please also tell us how you accounted for this deconsolidation and tell us whether you recognized a gain or loss in net income attributable to the parent. Refer to ASC 810-10-40.
- We note that you separately present the assets and liabilities held by variable interest entities on your balance sheet. In future filings, please recast your balance sheet to present the consolidated totals for each line item required by Rule 5-02 of Regulation S-X. Please note that you may state parenthetically after each line item the amount that relates to consolidated VIEs, or you may include a table following the consolidated balance sheets to present assets and liabilities of consolidated VIEs that have been included in the preceding balance sheet.

SEC staff comments have addressed the reporting entity's presentation of assets and liabilities of consolidated VIEs. When presenting assets, liabilities, and noncontrolling interests of a consolidated VIE, a reporting entity should present those items in the consolidated financial statements as if the basis for consolidating the VIE had been voting interests. ASC 810-10-45-25 requires a reporting entity to present on the face of the statement of financial position the (1) "[a]ssets of a consolidated [VIE] that can be used only to settle obligations of the consolidated VIE" and (2) "[l]iabilities of a consolidated VIE for which creditors (or beneficial interest holders) do not have recourse to the general credit of the primary beneficiary." A reporting entity must also satisfy the requirements related to (1) the elimination of intra-entity balances and transactions and (2) other matters discussed in ASC 810-10-45.

On the Horizon

As discussed in the [Acquisitions and Disposals](#) section, the FASB has issued a [proposed ASU](#) that would effectively narrow the definition of a business. If this proposal is finalized, fewer entities will qualify for the business scope exception.

Continued Evolution of the Consolidation Model?

There are no visible changes to the consolidation standard on the horizon. Are we entering another period in which only minor changes will be made to the consolidation requirements, such as the one enjoyed from 1959 to 2002? Or will economic conditions, transaction structures that continue to evolve in response to changing regulatory and tax environments, or FASB priorities or some combination thereof prompt further changes to address the future environment? Over the years, many of the amendments were designed to identify the appropriate consolidation framework for different types of legal entities. In the 1990s, the EITF made several attempts to define a special-purpose entity (SPE). For the last 12 years, practitioners have been applying the complex guidance on identifying a VIE. Although convergence with IFRSs has yet to be achieved, a single model under which a controlling financial interest can be determined regardless of whether a legal entity is a VIE would simplify the analysis.



Contingencies

Introduction

ASC 450 defines a contingency as an “existing condition, situation, or set of circumstances involving uncertainty . . . that will ultimately be resolved when . . . future events occur or fail to occur.” In the life sciences industry, contingencies often arise as a result of product liability issues; patent litigation cases, such as suits filed against the entity for patent infringement (e.g., generic at-risk launches); the uncertainty of achieving regulatory approval for a new drug; and compliance issues related to pricing, promotions, or manufacturing standards. In addition, for biotech and pharmaceutical firms, environmental issues and remediation proceedings have been the subject of considerable public and legislative discussion and initiatives. As a result, accounting standard setters such as the FASB, AICPA, and SEC have emphasized the accounting for and disclosure of environmental liabilities in the financial statements.



In the life sciences industry, a single event could trigger multiple contingencies, requiring an entity to separately evaluate each contingent liability to determine its appropriate recognition, measurement, and classification. For example, a regulatory action may result in the incurrence of incremental costs related to product recalls, leading to a change in product strategy, adjustments to customer sales allowances, or other events. Further, a litigation settlement may contain multiple elements, including cash payments, required future services, and other agreements or concessions between the parties.

The accounting for and disclosures about contingencies under ASC 450 differ depending on whether the contingency could result in a gain or a loss. In addition to providing general disclosure guidance on both gain and loss contingencies, ASC 450 discusses specific application of the guidance to unasserted claims, litigation, guarantees, and events occurring after the date of the financial statements but before their issuance, all of which are common in the life sciences industry.

ASC 450 defines a loss contingency as an “existing condition, situation, or set of circumstances involving uncertainty as to possible loss to an entity that will ultimately be resolved when one or more future events occur or fail to occur.” Accrual of an estimated loss contingency through a charge against earnings is required if it is probable that an asset has been impaired or a liability has been incurred as of the date of the financial statements and the amount of the loss can be reasonably estimated.

Companies must accrue the most likely estimate of the loss if it is possible to reasonably estimate a range of loss. If no amount within the possible range of loss is a better estimate than any other amount, companies must accrue for the lowest amount within that possible range of loss. If no amount is accrued for a loss contingency, or if a loss exposure is greater than the amount accrued, an entity must disclose the contingency when there is at least a reasonable possibility that a material loss or an additional material loss above the accrued amounts may have been incurred. Such disclosures should indicate the nature of the contingency and include an estimate of the possible range of loss or state that an estimate cannot be made.

A gain contingency arises if the outcome of future events may result in a possible gain or benefit to an entity (e.g., pending litigation whose outcome would result in a benefit). Unlike a loss contingency, a gain contingency is usually not reflected in the financial statements and should not be recorded in the financial statements before the contingency is realized. However, an entity must provide adequate disclosures about potential material gains and such disclosures should not lead to overly optimistic estimates regarding the likelihood of realizing a gain.

Featured Interpretive Guidance

The Q&As below contain guidance on contingency-related topics that frequently affect life sciences entities.

Product Recalls

Life sciences entities may be subject to recalls on their products (e.g., medical devices, pharmaceutical drugs). While some product recalls are voluntary (e.g., the drug manufacturer has chosen to take the drug off the shelves or notified consumers and doctors to stop using the product or return it), other recalls may be required by the FDA or other regulators.

Question

How should the liability recognition criteria of ASC 450-20-25 be applied to a product recall obligation?

Answer

Regarding the application of ASC 450-20 to product recalls, the obligating event triggering liability recognition is the announcement of a recall. Except as stipulated in the terms of a warranty arrangement, a company has no legal obligation or duty related to product design or manufacturing defects after the product is sold. Therefore, a probable loss would not arise until a recall is announced voluntarily or is mandated by regulators.

Offers to Settle Litigation

One of the major uncertainties in the life sciences industry is the risk of litigation. Class actions, individual suits, and actions brought by government agencies are not uncommon, and such contingencies may need to be accounted for or disclosed in the financial statements (e.g., a potential future obligation related to an uncertain amount resulting from past activities). With respect to pending or threatened litigation, ASC 450 requires the accrual of a loss contingency if certain criteria are met. Entities will often make offers to settle existing litigation; the accounting for the offer should be based on existing facts and circumstances associated with the litigation and related settlement.

Question

Does an offer by management to settle litigation need to be accrued in the financial statements?

Answer

An offer to settle litigation creates a strong presumption that it is probable that a liability has been incurred. The settlement offer presumably establishes a low end of the range under the guidance in ASC 450-20-30-1, resulting in accrual of a liability. Withdrawal of a settlement offer before acceptance and before issuance of the financial statements generally would not change this conclusion since the existence of the offer indicates that a probable obligation existed as of the date of the financial statements.

In limited circumstances, it might be possible to overcome the presumption that an offer to settle litigation triggers recognition of a probable loss. However, rebutting the presumption should be a high hurdle to overcome and should be based on persuasive evidence to the contrary. At a minimum, the evidence would need to substantiate that it is remote that (1) the offer will be accepted and (2) further negotiations will lead to an out-of-court settlement. One form of such evidence could be an unequivocal representation from legal counsel. A company that believes that the presumption has been overcome should consider consulting with its independent auditors or other accounting advisers.

Example

Company X is in the medical device business. Over the past year, X has been named as the defendant in a lawsuit alleging personal injury resulting from use of one of its surgical devices. After year-end, but before issuance of the annual financial statements, X offers to settle the litigation for \$1 million. Management of X contends that this offer was made solely to accelerate the process of resolving the dispute. The plaintiff has not responded to the offer. Company X believes that if the matter ultimately goes to trial, the plaintiff will not prevail with its claim.

The offer to settle is evidence that it is probable that a liability has been incurred as of the date of the financial statements and that the amount of the loss can be reasonably estimated. Company X should consider the guidance in ASC 450-20-30-1 in determining the appropriate amount to accrue. The amount of the offer establishes the low end of the range. If this amount is accrued, X must also consider the requirements related to the disclosure of any additional exposure to loss in its financial statements.

Thinking It Through

An entity should carefully consider all facts and circumstances when assessing whether an “offer” has been extended to settle litigation. For example, when the offer hinges on a counterparty’s performance of certain actions to which the entity believes the counterparty is not likely to agree, the entity may conclude that an offer has not been extended.

Accounting for Litigation Settlements When One or More Elements Exist

While some legal settlements in the life sciences industry involve only a single element (e.g., a claim or lawsuit over patent infringement), challenges often arise when a litigation settlement contains multiple elements.

Question

How should an entity account for a litigation settlement involving multiple elements?

Answer

An entity should identify each item given and received in the arrangement and determine whether such items should be recognized. At the 2007 AICPA National Conference on Current SEC and PCAOB Developments, Eric West, associate chief accountant in the SEC’s Office of the Chief Accountant, addressed how an entity should account for litigation settlements containing more than one element:

Elements of the Arrangement

To properly account for this arrangement, a company must identify each item given and received and determine whether those items should be recognized. We have found that errors generally occur when registrants don’t fully consider the nature of each item. . . .

Allocating Consideration to Each Item

An additional challenge that may arise when accounting for a litigation settlement is determining the proper allocation of consideration among the recognizable elements. While EITF [Issue] 00-21 [ASC 605-25] was written for multiple element revenue arrangements, we believe that its allocation guidance is also useful to determine how to allocate consideration paid in a multiple element legal settlement. In this regard, we believe that it would be acceptable to value each element of the arrangement and allocate the consideration paid to each element using relative fair values. To the extent that one of the elements of the arrangement just can’t be valued, we believe that a residual approach may be a reasonable solution. In fact, we have found that many companies are not able to reliably estimate the fair value of the litigation component of any settlement and have not objected to judgments made when registrants have measured this component as a residual. In a few circumstances companies have directly measured the value of the litigation settlement component.

Example

Mr. West gave the following example of a litigation settlement:

Assume a company pays cash and conveys licenses to a plaintiff in order to settle a patent infringement and misappropriation of trade secrets claim. In exchange for the payment and licenses given, the company receives a promise to drop the patent infringement lawsuit, a covenant not to sue with respect to the misappropriation of trade secrets claim, and a license to use the patents subject to the litigation.

In this arrangement, the items given include cash and licenses and the items received include the promise to drop the patent infringement lawsuit, the covenant not to sue, and the license to use the patents. After identifying these items and determining whether to recognize them, the company must use the relative fair value method or another approach (e.g., the residual value approach if one of the elements cannot be valued) to determine the proper allocation of consideration among the recognizable elements. Mr. West further clarified:

In the fact pattern that I just described, the company may be able to calculate the value of the settlement by applying a royalty rate to the revenues derived from the products sold using the patented technology during the infringement period. Admittedly, this approach requires judgment and we are willing to consider reasonable judgments.

Accounting for Liabilities When Demand for Payment Is Not Probable and Whether Legally or Contractually Required Liabilities Can Be Derecognized on the Basis of a Probability Assessment

In the life sciences industry, obligations to a third party, such as a customer or patent holder, may arise as a result of a law or contract that may be unknown to the third party, such as a royalty liability required by contract for the use of a patent. Such obligations should not be accounted for as loss contingencies under ASC 450-20 even if the third party is unaware of the obligation and unlikely to demand payment. Further, if an entity believes that a liability for which payment is required by law or contract will ultimately be settled for less than the stated legal obligation, the entity should not derecognize the liability (or a portion of the liability).

Question 1

Should a liability for which payment is required by law or contract be accounted for as a loss contingency under ASC 450-20 if it is uncertain whether the creditor is aware of the obligation and will demand payment?

Answer

No. Generally, the probability of payment is irrelevant if settlement of the liability is required by law or contract. That is, other than deferred revenues, liabilities established by law or contract should be recorded at their stated amounts unless GAAP require otherwise.

Paragraph 36 of FASB Concepts Statement 6 describes a liability as follows:

A liability has three essential characteristics: (a) it embodies a present duty or responsibility to one or more other entities that entails settlement by probable future transfer or use of assets at a specified or determinable date, on occurrence of a specified event, or on demand, (b) the duty or responsibility obligates a particular entity, leaving it little or no discretion to avoid the future sacrifice, and (c) the transaction or other event obligating the entity has already happened.

If an entity is required by current laws, regulations, or contracts to make a future payment associated with an event that has already occurred, that event imposes a present duty upon the entity. An entity's uncertainty about whether performance of an obligation will be required in the future does not allow the entity to choose to avoid the future sacrifice or relieve it of the obligation.

Once the obligating event has occurred, the probability of payment is not relevant in the determination of whether a contractual or legal obligation is a liability or a loss contingency. That is, when the obligating event has occurred, the entity has incurred a liability and there is thus no contingency.

In addition, a liability is not an unasserted claim or assessment under ASC 450-20 if the satisfaction of the liability is required by law or contract. The existence of the law or the contract constitutes an assertion of the claim.

Question 2

If an entity believes that a liability that is not deferred revenue, and for which payment is required by law or contract, will ultimately be settled for less than the stated legal obligation, can the liability be derecognized on the basis of a probability assessment of when and whether the creditor will demand payment?

Answer

No. ASC 405-20-40-1 states:

A debtor shall derecognize a liability if and only if it has been extinguished. A liability has been extinguished if either of the following conditions is met:

- a. The debtor pays the creditor and is relieved of its obligation for the liability. Paying the creditor includes the following:
 1. Delivery of cash
 2. Delivery of other financial assets
 3. Delivery of goods or services
 4. Reacquisition by the debtor of its outstanding debt securities whether the securities are cancelled or held as so-called treasury bonds.
- b. The debtor is legally released from being the primary obligor under the liability, either judicially or by the creditor. For purposes of applying [ASC 405-20], a sale and related assumption effectively accomplish a legal release if nonrecourse debt (such as certain mortgage loans) is assumed by a third party in conjunction with the sale of an asset that serves as sole collateral for that debt.

Example

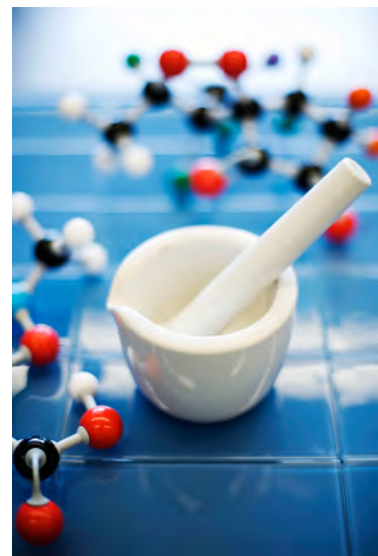
Company Y manufactures medical equipment and has a contractual obligation to pay, on the basis of sales volume, royalties to various patent holders. The amount of royalties paid in each period is calculated by Y. In accordance with this obligation, patent holders have the right to audit Y's sales volume, but they have rarely exercised this right.

Company Y should record a royalty liability for the full amount that it is contractually obligated to pay according to the royalty agreements. The liability should be adjusted upward as sales are made and should be adjusted downward only when the liability is paid or otherwise extinguished.

The contract requires Y to make royalty payments on the basis of sales volume. Therefore, Y is under an obligation to the patent holder as the equipment is sold (i.e., Y has a present duty to the patent holder). Company Y's uncertainty about whether a patent holder will audit the sales volume does not allow it to avoid future payment. Therefore, Y should not record a royalty liability for future sales until those sales actually occur. Further, if a patent holder cannot be located, the contractual liability should not be reduced until the escheat laws for that jurisdiction are complied with and the obligation no longer exists.

Events Occurring After the Date of the Financial Statements

Information that becomes available after the balance sheet date but before issuance of the financial statements may indicate that an asset was impaired or a liability incurred before the date of the financial statements. In the life sciences industry, events that occur after the balance sheet date may serve as confirmation of a condition that existed before the balance sheet date (e.g., the settlement of litigation that arose during prior periods covered by the financial statements and for which no liability had previously been recorded).



However, events occurring after the balance sheet date, such as the passage of new legislation, may be indicative of conditions that did not exist as of the balance sheet date. Financial statement disclosures about such events are only required if omission of such disclosures would cause the financial statements to be misleading.

Question

If legislation giving rise to a liability is enacted after the balance sheet date but before issuance of the financial statements, should a liability be accrued in the financial statements?

Answer

No. The enactment of a law after the balance sheet date but before issuance of the financial statements would be accounted for as a nonrecognized subsequent event (because the newly enacted law does not provide evidence about conditions that existed as of the balance sheet date). The entity should consider whether it is required to disclose the event to keep the financial statements from being misleading. The determination of when a law is considered enacted is a legal interpretation based on an entity's facts and circumstances.

Example

Entity A, a public entity with a December 31, 20X1, year-end, operates in the pharmaceutical industry and is subject to proposed legislation that will impose an excise tax on existing branded pharmaceuticals as of June 30, 20X1. The legislation is expected to be enacted after year-end but before the issuance of the financial statements. Entity A believes that because the legislation is probable and is related to balances as of a date before the balance sheet date, a liability should be accrued. However, the obligating event in this case is the enactment of the legislation, and A did not incur a liability before this event even though the tax was assessed on preexisting branded pharmaceuticals; thus, no liability should be accrued. Instead, the impact of the new legislation is a nonrecognized subsequent event and A should consider whether it is required to disclose the event to keep the financial statements from being misleading.

Favorable Legal Settlements

Contingencies that might result in gains usually are not reflected in the financial statements since to do so might be to recognize income before it is realized. Entities should provide adequate disclosures about contingencies that might result in gains and should be careful to avoid misleading implications regarding the likelihood of realization. The term "probable" is relevant to the accounting for a loss contingency, but it is not relevant to the accounting for a gain contingency. Realization must be assured beyond a reasonable doubt before a gain contingency can be recognized in the financial statements. Therefore, substantially all uncertainties, if any, about the timing and amount of realization of gain contingencies should be resolved before the contingencies are recognized in the financial statements.

Question

Is recognition of a gain contingency appropriate when a favorable verdict is returned in a court case?

Answer

Because of the numerous uncertainties inherent in a litigation proceeding, gain contingencies resulting from legal settlements generally cannot be recognized in income until cash or other forms of payment are received. This recognition threshold often results in the deferral of a gain even after a court rules in favor of a plaintiff.

Example

Company R was a plaintiff in a class action lawsuit against several drug manufacturers. After a lengthy appeals process, a settlement was reached. The funds were placed in an escrow account since an agreement had not been reached regarding the allocation of the settlement between the attorneys and each respective plaintiff. Because R does not know the timing or amount of cash to be received, gain recognition is inappropriate at this point.

Financial Statement Presentation and Disclosure Matters

Given the complex nature of many financial statement presentation and disclosure matters, highlighted below are matters that may be of greatest relevance to life sciences entities regarding discontinued operations, cash flows, carve-outs, and segment reporting.

Featured Interpretive Guidance

Discontinued-Operations Reporting

Introduction

While many life sciences entities have sought ways to expand their pipeline of products in development or to acquire additional commercial products, others have explored how to generate additional returns on assets that are no longer a strategic focus. When an entity sells a business or product line, questions often arise about whether the divested group of assets should be accounted for as a discontinued operation.

On April 10, 2014, the FASB issued [ASU 2014-08](#), which amends the definition of a discontinued operation in ASC 205-20 and requires entities to provide additional disclosures about disposal transactions that do not meet the discontinued-operations criteria. The revised guidance changes how entities identify and disclose information about disposal transactions under U.S. GAAP. The ASU elevates the threshold for a disposal transaction to qualify as a discontinued operation (since too many disposal transactions were qualifying as discontinued operations under existing guidance). Under the previous guidance in ASC 205-20-45-1, the results of operations of a component of an entity were classified as a discontinued operation if all of the following conditions were met:

- The component “has been disposed of or is classified as held for sale.”
- “The operations and cash flows of the component have been (or will be) eliminated from the ongoing operations of the entity as a result of the disposal transaction.”
- “The entity will not have any significant continuing involvement in the operations of the component after the disposal transaction.”

The new guidance eliminates the second and third criteria above and instead requires discontinued-operations treatment for disposals of a component or group of components that represents a strategic shift that has or will have a major impact on an entity’s operations or financial results. The ASU also expands the scope of ASC 205-20 to disposals of equity method investments and acquired businesses held for sale.

Further, the ASU (1) expands the disclosure requirements for transactions that meet the definition of a discontinued operation and (2) requires entities to disclose information about individually significant components that are disposed of or held for sale and do not qualify as discontinued operations.

The ASU also requires entities to reclassify assets and liabilities of a discontinued operation for all comparative periods presented in the statement of financial position. Before these amendments, ASC 205-20 neither required nor prohibited such presentation.

Regarding the statement of cash flows, an entity must disclose, in all periods presented, either (1) operating and investing cash flows or (2) depreciation and amortization, capital expenditures, and significant operating and investing noncash items related to the discontinued operation. This presentation requirement represents a significant change from previous guidance.



Scope

Previously, investments in equity securities accounted for under the equity method were outside the scope of ASC 205-20. The ASU eliminates that scope exception. In addition, the ASU notes that a “business or nonprofit activity that, on acquisition, meets the criteria to be classified as held for sale is reported in discontinued operations.” Further, the ASU removes the discontinued-operations scope exceptions in ASC 360-10-15-5 but retains the exception for oil and gas properties accounted for under the full-cost method.

Recognition Criteria

Under the revised guidance, the unit of account for evaluating disposals (other than an acquired business or nonprofit activity) continues to be a component of an entity or a group of components of an entity; the ASU retains the existing definition of a component of an entity.

Discontinued Operation

ASU 2014-08 defines a discontinued operation as a component or group of components of an entity that (1) has been disposed of by sale or other than by sale in accordance with ASC 360-10-45-15, or is classified as held for sale, and (2) “represents a strategic shift that has (or will have) a major effect on an entity’s operations and financial results.” According to the ASU, a strategic shift that has (or will have) a major effect on an entity’s operations and results includes the disposal of any of the following:

- A major geographical area.
- A major line of business.
- A major equity method investment.
- Other major parts of an entity.

The ASU does not define the terms “major,” “line of business,” or “geographical area.” It does, however, provide examples illustrating the evaluation of whether a disposal qualifies as a discontinued operation. These examples illustrate the quantitative thresholds of various metrics (e.g., assets, revenue, net income) — ranging from 15 percent to 20 percent as of the disposal date and 30 percent to 40 percent in historical periods — in various scenarios in which there was a strategic shift in an entity’s operations that has (or will have) a major effect on the entity’s financial results.

Thinking It Through

Entities need to use judgment in determining what constitutes “major.” Some may interpret the illustrative guidance in ASC 205-20-55-83 through 55-101 as implying that breaching quantitative thresholds in the range of 15 percent to 20 percent indicates that a disposal is major. However, note that the FASB intentionally avoided creating a bright-line quantitative threshold because qualitative factors may also affect this assessment.

Entities may also find it challenging to define the terms “line of business” and “geographical area.” For example, some entities may define a geographical area as a county, state, country, or continent, while others may base this definition on how management determines its regions. In addition, there may be differences in how entities define a major line of business: some may weight quantitative considerations more heavily, while others may stress qualitative factors.

Further, at the 2015 AICPA Conference on Current SEC and PCAOB Developments, SEC Associate Chief Accountant Barry Kanczucker noted that entities will need to use judgment when applying the new discontinued-operations guidance in ASU 2014-08 on determining when a component or group of components that has been disposed of or classified as held for sale represents a “strategic shift that has (or will have) a major effect on an entity’s operations and financial results.” In considering how an entity should determine what constitutes a financial result, Mr. Kanczucker observed that certain “primary” metrics, such as revenue, total assets, and net income, are prominently presented in the financial statements and communicated to investors. However, he also noted that an entity may have to exercise judgment to identify other financial results when performing an evaluation of major effect, “with an eye toward what is relevant from an investor’s perspective.” Mr. Kanczucker indicated that it may be helpful to understand alternative measures since certain operating metrics may also be relevant, particularly when the company has consistently used those measures to communicate operating and financial results. Further, he observed that “it is prudent to consider the effect of [a] relevant financial metric on the entity from the perspective of current, historical and forecasted results.”

Disclosures

The ASU introduces several new disclosure requirements for both (1) disposals that meet the criteria for a discontinued operation and (2) individually significant disposals that do not meet these criteria.

The following are some of the noteworthy new disclosure requirements:

- Major line items constituting the pretax profit or loss for all periods for which the discontinued operation’s results of operations are reported in the income statement. Some examples of major line items are (1) revenue, (2) cost of sales, (3) depreciation and amortization, and (4) interest expense.
- For most discontinued operations, an entity must disclose either of the following in the statement of cash flows or the notes to the financial statements:
 - Operating and investing cash flows for the periods for which the discontinued operation’s results of operations are reported in the income statement.
 - Depreciation and amortization, capital expenditures, and significant operating and investing noncash items for the periods for which the discontinued operation’s results of operations are reported in the income statement.
- “For the initial period in which the disposal group is classified as held for sale and for all prior periods presented in the statement of financial position, a reconciliation of” (1) total assets and total liabilities of the discontinued operation that are classified as held for sale in the notes to the financial statements to (2) “[t]otal assets and total liabilities of the disposal group classified as held for sale that are presented separately on the face of the [balance sheet].”
- For disposal of an individually significant component that does not meet the definition of a discontinued operation, all entities must disclose pretax profit or loss reported in the income statement for the period in which the disposal group is sold or is classified as held for sale. In addition, public entities must also disclose pretax profit or loss for all prior periods presented in the income statement.

These disclosures are required for both interim and annual reporting periods.

Transition Guidance

The ASU was effective prospectively for all disposals (except disposals classified as held for sale before the adoption date) or components initially classified as held for sale in periods beginning on or after December 15, 2014.

See Deloitte’s April 22, 2014, [Heads Up](#) for further discussion of ASU 2014-08.

Q&As on Applying ASU 2014-08

The Q&As below address common accounting issues related to the application of ASU 2014-08.

Allocated Corporate Overhead Costs

Question

May an entity include allocated corporate overhead costs in the discontinued operations of a component (or group of components) of the entity?

Answer

An entity may include only those costs that (1) are clearly identifiable as costs of the component (or group of components) being disposed of and (2) will not be recognized on a going-concern basis by the entity.

Example 1

A company has a general workers' compensation insurance policy for all of its divisions, which is allocated to each division on the basis of the number of employees in that division. The company is disposing of one of its divisions; as a result of such disposal, the company's insurance rates will be reduced by \$1 million. Accordingly, it is appropriate for the company to include the insurance costs of the division being disposed of in discontinued operations.

Example 2

A company allocates the salary costs of its executive committee to all of its divisions on the basis of total revenues. No executive has direct responsibility for the division being disposed of; however, two executives will be transferred with the division. The company may not include the salaries of the transferred executives in discontinued operations.

Intercompany Sales

Question

Company N, a pharmaceutical manufacturing company with plants around the country, owns Company X, a distribution business that buys drugs from N and then sells the drugs to outside customers. Company N is planning to discontinue the operations of X and sell X to another entity. Because N has appropriately eliminated the intercompany sales between itself and X, it recognizes only the sales from X to the customers.

Company X will continue to purchase drugs from N to sell to outside customers. Therefore, N will continue to have sales to X that will not be eliminated once X is no longer a related party. Company N has determined that the disposal of X's operations represents a strategic shift that will have a major effect on N's operations. Therefore, X will be classified as a discontinued operation in the second-quarter financial statements.

May the intercompany sales between N and X that have not been passed on to outside customers remain in continuing operations?

Answer

Yes, N's sales to X that have not been passed on to outside customers should be shown in N's continuing operations. For example, N sells drugs to X for \$6 with a cost of \$4. Company N's profit is \$2. Company X sells drugs to outside customers for \$7 with a cost (X's purchase price from N) of \$6. Company X's profit is \$1. In N's consolidated financial statements, the intercompany sales of \$6 will be eliminated along with the \$6 cost of sales, leaving a profit of \$3. The \$3 margin will come through as \$2 in continuing operations (representing N's sales to X) and \$1 in discontinued operations (representing X's sales to the outside customers). Next year (assuming the same facts), when N sells drugs to X, N will have the same \$6

sale, \$4 cost of sale, and \$2 profit in its continuing operations (and will not have the additional \$1 profit from sales to the outside customers).

Company N should record sales from continuing operations of \$6, cost of sales of \$4, a profit of \$2, and \$1 of profit in discontinued operations.

Earnings per Share Presentation

Question

Should earnings per share amounts be shown separately when an entity reports discontinued operations?

Answer

Yes. ASC 260-10-45-3 requires an entity that reports discontinued operations to present basic and diluted per-share amounts for discontinued operations either on the face of the income statement or in the notes to the financial statements. This disclosure is required in addition to the required presentation of basic and diluted earnings per share amounts for income from continuing operations and net income, both of which should be shown on the face of the income statement with equal prominence.

Balance Sheet Presentation of a Disposal Group Held for Sale

Question

As of March 15, 20X2, Company F had committed to a qualifying plan to dispose of its wholly owned subsidiary, Company J, by sale and will treat J as a discontinued operation because J met the criteria in ASC 205-20-45-1A through 45-1G. How should F present the assets and liabilities of J in its consolidated balance sheet for F's first quarter ending March 31, 20X2, and year ended December 31, 20X1?

Answer

Company F would be required to present the assets and liabilities of J separately in the asset and liability sections of the consolidated balance sheet for the first quarter ending March 31, 20X2; it should not offset the assets and liabilities of J and present them as a single amount. In addition, F would be required to reclassify the assets and liabilities of J presented in F's consolidated balance sheet as of December 31, 20X1, to conform their presentation to the presentation required in the March 31, 20X2, consolidated balance sheet.

Carve-Outs

Introduction

Carve-out financial statements are commonly prepared for divestments of businesses in transactions involving life sciences entities. A carve-out occurs when a parent company segregates a portion of its operations and prepares a distinct set of financial information in preparation for a sale, spin-off, or divestiture of the "carve-out entity." The carve-out entity may consist of all or part of an individual subsidiary, multiple subsidiaries, or even an individual segment or multiple segments. In some cases, one or more portions of a previously consolidated parent company's subsidiaries may create the newly defined carve-out operations.

"Carve-out financial statements" is a generic term used to describe separate financial statements that are derived from the financial statements of a larger parent company. The form of those financial statements may vary, however, depending on the situation. For example, if the acquisition is small, a strategic buyer of a carve-out entity may be satisfied with an unaudited balance sheet and income statement for the most recent fiscal year. Another public buyer, however, may require a full set of SEC-compliant audited financial statements, including footnotes, for the three most recent fiscal years, while

yet a third buyer might ask that the periods be audited but be completely unconcerned with SEC reporting considerations. Accordingly, assessing the potential audience is critical to understanding the basis of presentation and the number of periods needed. Such an assessment can be particularly tricky when the carve-out financial statements are being prepared before the buyer or potential buyers are identified.

Identifying the Carve-Out Entity

Once the purpose of the carve-out transaction has been identified, management should turn its attention to defining the operations to be included in the carve-out. This is the most important step in the carve-out process. If management were to incorrectly identify the operations to be included in the carve-out, the carve-out financial statements would be misstated regardless of whether the appropriate periods were presented and revenues/expenses and assets/liabilities were reasonably allocated.

Identifying the carve-out operations can be complex because there is currently no detailed accounting guidance on preparing carve-out financial statements. In a best-case scenario, the terms and conditions of the purchase-and-sale agreement will outline the assets and liabilities and legal entities that the carve-out entity comprises. However, it is more difficult to prepare carve-out financial statements for a spin-off or divestiture in advance of a formal agreement.

Carve-out financial statements should present information about all aspects of the carve-out entity's historical results and operations (i.e., provide balanced and transparent financial information that reflects all of the operation's historical successes and failures). Foresight and future business decisions should not be incorporated into the carve-out financial statements. In instances in which the carve-out financial statements may include assets or operations that will not be part of the ultimate carve-out transaction, an entity would typically provide pro forma financial information to adjust the historical carve-out financial statements to reflect only the net assets and operations being carved out.

Historical Results and Operations

A segment or reporting unit¹ with defined financial results may be a good starting point for identification of the carve-out entity; often, however, only a portion of a segment or reporting unit is being divested, increasing the difficulty of identifying the assets and liabilities related to the carve-out entity. Management must consider where certain employees and assets will reside after the carve-out transaction. Understanding whether these individuals and assets represent a portion or all of certain operating, reporting, or legal structures may help illuminate the appropriate basis of presentation.

Management must also evaluate whether an entire entity or multiple entities are being divested or whether only portions of one or more entities are being carved out. In preparing the historical financial statements, management must consider any prior restructuring activities. That is, management needs to evaluate any historical acquisitions or divestitures to determine whether to include them in the historical periods. In a speech at the 2001 AICPA National Conference on Current SEC Developments, SEC staff member Leslie Overton indicated that if the carve-out entity, for example, is a registrant or will undergo an IPO, the carve-out financial statements "should include all relevant activities that have been a part of the history of the business and that can be expected to repeat as the business continues in the future."

Legal Structure

Because it directly affects the nature of the carve-out financial statements and can be used as a basis for evaluation of the historical financial results, the legal structure of the carve-out is critical. However, in some instances, the legal structure is often established for tax purposes and may include portions of or complete product lines or geographies that may not align with the carve-out entity. A carve-out may be a single legal entity (or a portion of a single entity), a group of legal entities, various business lines with no legal entity status, or a combination of these. Management must consider both the accounting and income tax implications of including certain legal entities in (or excluding them from) the carve-out entity. In many cases, detailed financial information may not be readily available on an entity-by-entity level.

¹ ASC 350-20-20 defines a reporting unit as "an operating segment or one level below an operating segment (also known as a component)."

Cash Flows

The accounting principles related to the statement of cash flows have been in place for many years. However, errors in the statement of cash flows remain one of the leading causes of restatements, and companies continue to receive comments from the SEC staff on cash flow presentation matters. Further, while ASC 230 provides some guidance on cash payments and receipts that are classified as operating, investing, or financing activities, its lack of consistent principles for evaluating the classification of cash payments and receipts in the statement of cash flows has led to diversity in practice. In light of this, we have highlighted below interpretive cash flow guidance most pertinent to the life sciences industry.

How Acquisitions for Stock Are Classified in the Statement of Cash Flows

Question

Company A acquired 100 percent of the common stock of Company B in exchange for issuing 10,000 shares of A's stock. How should this transaction be classified on A's statement of cash flows?

Answer

Because the acquisition of B involved no cash consideration, the transaction should be disclosed as a noncash investing (acquisition of B) and noncash financing (issuance of A's stock) transaction. Disclosure may consist of a narrative or be summarized in a schedule. ASC 230-10-50-3 states:

Information about all investing and financing activities of an entity during a period that affect recognized assets or liabilities but that do not result in cash receipts or cash payments in the period shall be disclosed. Those disclosures may be either narrative or summarized in a schedule, and they shall clearly relate the cash and noncash aspects of transactions involving similar items.

In addition, A would generally classify B's acquired cash and cash equivalents, if any, as an investing activity in the statement of cash flows. In certain circumstances, however, the predominant source of cash acquired in a business combination may be more appropriately characterized as financing (e.g., if B had recently issued debt and the acquired cash balance largely comprised the proceeds from that borrowing).

Presentation of Business Combinations Paid for in Part by Stock and in Part by Cash in the Statement of Cash Flows

Question

How should business combinations paid for in part by stock and in part by cash be presented in the statement of cash flows?

Answer

Acquisitions for stock are considered noncash investing and financing activities and should be disclosed in a narrative or summarized in a schedule in the financial statements. Correspondingly, acquisitions paid for in part by cash and in part by stock should be split between the cash and noncash aspects of the transaction. Only the cash portion is reported as an investing activity in the statement of cash flows. The stock portion is disclosed. The amount of cash paid, net of the acquiree's cash and cash equivalents, is presented as an investing cash outflow, as illustrated in the following example.

Example — Cash Paid in Acquisition Exceeds Cash Acquired in Acquisition

Company A acquires Company B for 10,000 shares of Company A's stock (fair value of \$100 per share) and \$150,000 cash. Company B's net assets have a fair value of \$1,150,000, which includes \$50,000 of cash and cash equivalents. Company A reflects the transaction in its statement of cash flows and related disclosures as follows:

- Noncash investing and financing activity of \$1,000,000.
- Investing cash outflow of \$100,000 for cash paid in acquisition, net of cash acquired.

Classification of Contingent Consideration in the Income Statement and Statement of Cash Flows

ASC 805 requires the acquirer to recognize the acquisition-date fair value of the contingent consideration arrangement as part of the consideration transferred in exchange for the acquiree. The contingent consideration arrangement is classified either as a liability or as equity in accordance with applicable U.S. GAAP.

Question

What is the appropriate classification in the income statement and statement of cash flows for amounts associated with contingent consideration arrangements (measured as of the acquisition date) and for subsequent changes to these amounts?

Answer

Contingent Consideration Classified as a Liability

If the acquiring entity determines that the contingent consideration arrangement should be classified as a liability, the initial fair value of the contingent consideration as of the acquisition date should be reflected as a **noncash** investing activity. In accordance with ASC 230-10-50-3, this arrangement should be either disclosed narratively or summarized in a schedule because no cash consideration is transferred on the acquisition date. It should not be reflected in investing activities. In subsequent periods, the contingent consideration liability must be remeasured at fair value as of each reporting date until the contingency is resolved, with the changes recognized as an operating expense in the determination of earnings (unless the change is the result of a measurement-period adjustment² or the arrangement is a hedging instrument for which ASC 815 requires changes to be recognized in other comprehensive income). Because the subsequent fair value adjustment enters into the determination of the acquiring entity's net income and is a noncash item, it should be reflected as a reconciling item between net income and cash flows from operating activities in the statement of cash flows.

If the contingent consideration is satisfied in either cash or cash equivalents upon resolution of the contingency, the amount paid to settle the contingent consideration liability should be separated into its two components. First, the cash paid to settle the contingent consideration liability recognized at fair value as of the acquisition date (including measurement-period adjustments) should be reflected as a cash outflow from financing activities in the statement of cash flows in accordance with ASC 230-10-45-13(c). Effectively, the acquiring entity financed the acquisition, and the cash outflow represents a subsequent payment of principal on the borrowing and should be reflected in accordance with ASC 230-10-45-15. Second, the remaining portion of the amount received/paid (i.e., the changes in fair value of the contingent consideration liability after the acquisition date) should be reflected as a cash inflow/outflow from operating activities because the fair value adjustments were recognized in earnings. If the amount paid to settle the contingent consideration liability is less than the amount recorded on the acquisition date (i.e., the fair value of the contingent consideration decreased), the entity would only reflect the portion of the liability that was paid as a cash outflow from financing activities. The difference between the liability and the amount paid is a fair value adjustment. This adjustment enters into the determination of the acquiring entity's net income and is a noncash item, so it should be reflected as a reconciling item between net income and cash flows from operating activities in the consolidated statement of cash flows.

The above guidance does not apply to contingent consideration that is resolved within three months or less of the acquisition date. If the contingent consideration is paid within three months or less of the acquisition date, settlement of the contingent consideration liability as of the acquisition date (including measurement-period adjustments) would not be viewed as a borrowing arrangement and the cash outflow would be reflected as an investing activity under ASC 230-10-45-13.

² Acquirers generally have a period of up to one year to finalize the acquisition-method accounting. Measurement-period adjustments are adjustments made during such a period to the provisional amounts recorded by the acquirer as of the acquisition date. The adjustments must relate to new information obtained about facts and circumstances that existed as of the acquisition date. See ASC 805-10-25-13 through 25-19, ASC 805-10-30-2 and 30-3, and ASC 805-30-35-1 for more information about measurement-period adjustments, including what qualifies as a measurement-period adjustment.

Example 1

On December 1, 20X0, Company A (a calendar-year-end, private company) acquired 100 percent of Company B for \$1 million. The purchase agreement includes a contingent consideration arrangement under which A agreed to pay additional cash consideration if the earnings of B (which will be operated as a separate subsidiary of A) exceed a specified target for the year ending December 31, 20X1. Company A classified the contingent consideration arrangement as a liability and recorded the contingent consideration liability at its acquisition-date fair value amount, provisionally determined to be \$500,000.

On April 15, 20X1, A finalized its valuation of the contingent consideration liability. Therefore, A estimated the acquisition-date fair value of the contingent consideration liability to be \$600,000 and recorded a measurement-period adjustment for \$100,000 (the measurement-period adjustment related to facts and circumstances that existed as of the acquisition date), with an offsetting adjustment to goodwill.

Company B achieved the performance target for the year ended December 31, 20X1; accordingly, A determined that it must pay \$750,000 to B's former owners to settle the contingent consideration arrangement. For the year ended December 31, 20X1, A recognized \$150,000 ($\$750,000 - \$600,000$) in earnings to reflect the subsequent remeasurement of the contingent consideration liability to fair value. On January 31, 20X2, A settled the obligation.

Company A would present the following amounts in its statement of cash flows for the years ended:

- *December 31, 20X0* — The provisional accrual of \$500,000 would be reflected as a noncash investing activity and would be either disclosed narratively or summarized in a schedule.
- *December 31, 20X1*:
 - The adjustment to the provisional accrual of \$100,000 would be reflected as a noncash investing activity and would be either disclosed narratively or summarized in a schedule.
 - The subsequent remeasurement adjustment to the contingent consideration liability of \$150,000 would be reflected as a reconciling item between net income and cash flows from operating activities.
- *December 31, 20X2*:
 - Of the \$750,000 paid, \$600,000 represents the amount to settle the contingent consideration liability recognized at fair value as of the acquisition date (including measurement-period adjustments) and should be reflected as a cash outflow from financing activities.
 - The remaining portion of the \$750,000 paid (i.e., the \$150,000 change in fair value of the contingent consideration liability after the acquisition date) should be reflected as a cash outflow from operating activities because the fair value adjustments were recognized in earnings.

Example 2

Assume the same facts as in Example 1, except that when Company B achieved the performance target for the year ended December 31, 20X1, A determined that it only needed to pay \$550,000 to B's former owners to settle the contingent consideration arrangement. For the year ended December 31, 20X1, A recognized a credit of \$50,000 ($\$550,000 - \$600,000$) in earnings to reflect the subsequent remeasurement of the contingent consideration liability to fair value.

Company A would present the same amounts as those in Example 1 in its statement of cash flows for the year ended December 31, 20X0. Company A would then present the following amounts for the years ended:

- *December 31, 20X1*:
 - The adjustment to the provisional accrual of \$100,000 would be reflected as a noncash investing activity and would be either disclosed narratively or summarized in a schedule.
 - The subsequent remeasurement adjustment to the contingent consideration liability of \$50,000 would be reflected as a reconciling item between net income and cash flows from operating activities.

- *December 31, 20X2* — The entire amount of the \$550,000 paid represents the amount to settle the contingent consideration liability recognized at fair value as of the acquisition date (including measurement-period adjustments) and should be reflected as a cash outflow from financing activities.

Contingent Consideration Classified as Equity

If the acquiring entity determines that the contingent consideration arrangement should be classified as equity, it is not required to remeasure the amount recorded as of the acquisition date at fair value as of each reporting period after the acquisition date. The initial recognition of the contingent consideration arrangement as of the acquisition date (including measurement-period adjustments), and the issuance of shares to settle the contingent consideration arrangement on the date the contingency is resolved, should be reflected as noncash investing and financing activities and, in accordance with ASC 230-10-50-3, should be either disclosed narratively or summarized in a schedule.

Classification of the Settlement of an Acquired Liability Subsequent to a Business Combination in the Statement of Cash Flows

Question

How should a payment made to settle a liability that was acquired in connection with a business combination be presented in the statement of cash flows?

Answer

Depending on the nature of the payment, the cash outflow could be classified as an operating, investing, or financing activity. The payment should be classified as it would have been in the absence of the business combination. Consider the following scenarios:

- If the payment was for inventory purchased on account, it would represent an operating cash outflow.
- If the payment was for property, plant, and equipment that was purchased on account and was paid within three months of its original purchase date, it would represent an investing cash outflow.
- If the payment was in connection with outstanding debt, it would represent a financing cash outflow.

Classification of Acquisition of Property, Plant, and Equipment on Account

Question

When the indirect method is used, if the beginning or ending accounts payable balance includes amounts related to the acquisition or construction of property, plant, and equipment and other productive assets, should the change in accounts payable reflected in the operating activities section of the statement of cash flows be adjusted for such amounts?

Answer

Yes. ASC 230-10-45-29 states that the reconciliation of net income to net cash flow from operating activities must separately report all major classes of reconciling items, "including, at a minimum, changes during the period . . . in payables pertaining to operating activities."

Therefore, any changes in payables related to investing or financing transactions should be segregated from changes in operating accounts payable.

Accordingly, in the period the liability is incurred to acquire or construct such an asset, the change in accounts payable in the operating section of the cash flow statement should not include the amount of any unpaid liability that was incurred during the current reporting period to acquire or construct the asset; rather, such amount should be disclosed as a noncash investing activity, either in narrative disclosure or summarized in a schedule. The amount disclosed as a noncash investing

activity should reflect only the amount of assets acquired during the current reporting period by incurring liabilities that remain unpaid as of the end of the reporting period, and not merely the period-to-period change in the liability account used to track productive assets purchased on account.

In the period the liability is paid, the amount should be reflected as a cash outflow for investing activities or financing activities, depending on the payment terms of the transaction.

Example

In December 20X4, Company A purchased equipment from a supplier on account for \$500,000, which was included in the total year-end accounts payable balance of \$4 million. Company A paid the \$500,000 payable due to the supplier in January 20X5. In December 20X5, A purchased equipment from a supplier on account for \$1 million, which was included in the total year-end accounts payable balance of \$6 million. Company A paid the \$1 million payable due to the supplier in January 20X6.

In preparing its 20X5 cash flow statement, A would (1) reduce the total \$2 million increase in accounts payable by the \$500,000 change in nonoperating accounts payable and report a total increase in operating accounts payable of \$1.5 million; (2) present an investing cash outflow for the \$500,000 payment made in January 20X5; and (3) disclose a noncash investing activity of \$1 million, representing the unpaid liability that was incurred during 20X5 to acquire equipment.

In preparing its 20X6 cash flow statement, A would reflect the \$1 million decrease in accounts payable as an investing activity outflow for the acquisition of the equipment.

Determining Whether the Acquisition of Property, Plant, and Equipment on Account Is an Investing or Financing Activity

Question

ASC 230-10-45-13(c) describes payments “at the time of purchase or soon before or after purchase to acquire property, plant, and equipment and other productive assets” as a source of cash outflows for investing activities. What does the term “soon” mean in this context?

Answer

The SEC staff has informally interpreted the term “soon” in this context to be a period of three months or less. This period is consistent with the period used for other ASC 230 considerations (e.g., the definition of “cash equivalents” in ASC 230-10-20, and the determination of net or gross presentation in ASC 230-10-45-9). Therefore, if a company purchases property, plant, and equipment and other productive assets, and the terms of the transaction require payment within three months of the transaction date, the payment would be classified as an investing outflow. If the payment terms of the transaction extend beyond three months, any payment made after three months would be classified as a financing outflow.

Segments

Introduction

ASC 280-10-10-1 states that the “objective of requiring disclosures about segments of a public entity and related information is to provide information about the different types of business activities in which a public entity engages and the different economic environments in which it operates to help users of financial statements do all of the following:

- a. Better understand the public entity’s performance
- b. Better assess its prospects for future net cash flows
- c. Make more informed judgments about the public entity as a whole.”

ASC 280 requires that general-purpose financial statements include selected information reported on a single basis of segmentation. The method for determining what information to report is referred to as the management approach. ASC 280-10-05-3 states that the “management approach is based on the way that management organizes the segments within the public entity for making operating decisions and assessing performance. Consequently, the segments are evident from the structure of the public entity’s internal organization, and financial statement preparers should be able to provide the required information in a cost-effective and timely manner.”

ASC 280-10-05-4 further provides that the “management approach facilitates consistent descriptions of a public entity in its annual report and various other published information. It focuses on financial information that a public entity’s decision makers use to make decisions about the public entity’s operating matters. The components that management establishes for that purpose are called operating segments.”

Identifying Operating Segments

ASC 280-10-50-1 defines an operating segment as “a component of a public entity that has all of the following characteristics:

- a. It engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same public entity).
- b. Its operating results are regularly reviewed by the public entity’s chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance.
- c. Its discrete financial information is available.”

According to ASC 280-10-50-5, the term “chief operating decision maker” (CODM) “identifies a function, not necessarily a manager with a specific title. That function is to allocate resources to and assess the performance of the segments of a public entity. Often the [CODM] of a public entity is its chief executive officer or chief operating officer, but it may be a group consisting of, for example, the public entity’s president, executive vice presidents, and others.”

Thinking It Through

The SEC staff has noted recently in a number of forums that it expects to renew its emphasis on identifying an entity’s CODM. While most entities identify their chief executive officer (CEO) as their CODM, the SEC staff has noted that there could be instances in which, after responding to the staff’s questions, an entity changes its conclusion regarding the CODM, such as to a chief operating officer or to a committee. Because these individuals often review more disaggregated operating results than the CEO, such a change in the CODM can affect the entity’s conclusions about its operating segments. As a result, the SEC staff has indicated that it would also focus on understanding the management structure (e.g., through organizational charts or other information) supporting the person (or group) identified as the CODM.

A characteristic of an operating segment is that its operating results are regularly reviewed by the public entity’s CODM, who decides about resources to be allocated to the segment and assesses its performance.

Thinking It Through

Historically, when evaluating an entity's operating segments, the SEC staff has placed a great deal of emphasis on the information regularly provided to and reviewed by the CODM. The SEC staff would frequently request copies of the CODM package as well as the information provided to the entity's board of directors and would attempt to reconcile that information to the entity's operating segments.

In its December 2012 PIR [report](#) on FASB Statement 131, the FAF observed that “[a]dvances in information technology also make the guidance for determining operating segments more difficult to apply and audit. Technology allows more detailed financial information to be available to the CODM. The ability of the CODM to access more detail makes less clear what the CODM ‘receives’ and ‘regularly reviews.’ As a result, it might be more difficult to determine operating segments and less clear how to aggregate them.”

Partly in response to the FAF's observation, the SEC staff has recently noted in a number of forums that its historical views regarding an entity's CODM package are evolving and that in the past it may have overemphasized the importance of the CODM package. The SEC staff indicated that rather than viewing the CODM package as the determinative factor in identifying operating segments, it would consider the CODM package as only one of many factors in the determination.³ Similarly, the SEC staff noted that it would not view the CODM package as a safe harbor for entities. That is, the staff might conclude that other, potentially conflicting information overcomes the absence of operating results in the CODM package for a potential operating segment. Entities should expect the SEC staff to:

- Question whether there are disaggregated operating results not included in the CODM package that are nonetheless regularly reviewed by the CODM.⁴
- Continue to review other publicly available information for consistency with the entity's segment disclosures, such as the information in the forepart of the Form 10-K (i.e., the business section and MD&A), the entity's Web site, analysts' reports, and press releases.⁵

The SEC staff's recent comments also serve to remind entities that the method used for segment reporting is the “management approach,” which is based on an entity's internal organization, and that an entity's organizational charts may reflect its internal structure better than the information routinely provided to the CODM or CODM group, especially in light of the above-noted observation in the FAF's PIR report on FASB Statement 131.

Aggregating Operating Segments

ASC 280-10-50-11 permits entities to aggregate two or more operating segments into a single operating segment “if aggregation is consistent with the objective and basic principles of [ASC 280-10], if the segments have similar economic characteristics, and if the segments are similar in all of the following areas . . . :

- a. The nature of the products and services
- b. The nature of the production processes
- c. The type or class of customer for their products and services
- d. The methods used to distribute their products or provide their services
- e. If applicable, the nature of the regulatory environment, for example, banking, insurance, or public utilities.”

It is presumed that users would prefer disaggregated information and that operating segments should be aggregated only if providing more detailed information would not enhance a user's understanding of the entity.

³ Entities should consider all available information in determining how the CODM makes decisions to allocate resources and assess performance, including understanding the process and discussions that occur in the CODM's regular meetings (weekly, monthly, or quarterly) with other members of management.

⁴ If the information in the CODM package is too high-level, the SEC staff will ask entities to explain how performance problems can be identified or alternative allocations of limited resources can be evaluated if the CODM does not use more disaggregated operating information.

⁵ Serious questions are raised when financial information released to analysts or the financial press differs from the information in the entity's segment disclosures.

Thinking It Through

ASC 280 requires disclosure if operating segments have been aggregated. When evaluating an entity's reported segments, the SEC staff has routinely requested clarification about whether operating segments have been aggregated and, if so, the analysis performed in concluding aggregation is appropriate. The SEC staff expects the entity's analysis to address whether aggregation is consistent with the objectives and basic principles of ASC 280, as well as how the entity determined that providing more detailed segment disclosure would detract from these objectives.

ASC 280-10-50-11 states that "[o]perating segments often exhibit similar long-term financial performance if they have similar economic characteristics. For example, similar long-term average gross margins for two operating segments would be expected if their economic characteristics were similar." There are no bright lines in the evaluation of whether two or more operating segments possess similar economic characteristics. That is, ASC 280 does not define the term "similar" or provide guidance on the time horizon of historical and expected future periods to be evaluated. ASC 280 provides "long-term average gross margins" and "sales trends" only as examples of the measures to be considered and does not indicate what other measures are acceptable⁶ or what would be an acceptable spread between those measures. Accordingly, an entity is required to use significant judgment when it elects to aggregate operating segments, and good documentation of its judgment is paramount. Recent comments from the SEC staff suggest that challenges in this area will continue and that the staff may ask entities to explain and defend the reasonableness of the judgment they applied.

Presentation of segments was a hot topic at the 2015 AICPA Conference on Current SEC and PCAOB Developments. In a [speech](#) delivered at the conference, Courtney Sachtleben, professional accounting fellow in the SEC's Office of the Chief Accountant, reiterated views on segment reporting expressed by the SEC staff last year. In addition, Ms. Sachtleben observed that appropriate application of the guidance in ASC 280 will sometimes result in the identification of a single operating segment, which "can be a significant signal to investors about how management has allocated resources." In these circumstances, "registrants should disclose that they allocate resources and assess financial performance on a consolidated basis and should explain the basis for that management approach [since it] would seem counter to the objectives of segment reporting if the business description indicates the entity is diversified across businesses or products, yet is not managed in a disaggregated way."

Further, Ms. Sachtleben discussed management's controls related to segment reporting, noting that an entity is required to use reasonable judgment when applying the guidance on segment reporting. She indicated that effective internal control over financial reporting (ICFR) would support the entity's judgment-based determinations, such as those related to operating segments, aggregation, and entity-wide disclosures. Engagement with the CODM to determine how it allocates resources and assesses performance may be important in the design of effective ICFR. Ms. Sachtleben added that "documenting the design and effective operation of management's controls over [the entity's judgment-based determinations] is an integral part of management's support for the effectiveness of its ICFR . . . and will be essential to the auditor's ability to evaluate these controls."

⁶ Entities may decide to look to other performance measures such as operating cash flows; return on assets, earnings before interest, taxes, depreciation, and amortization (EBITDA); inventory turnover; or other standard industry measures. These factors should be evaluated from both a historical and "expected future performance" perspective. However, an expectation of similar long-term economic performance is not sufficient alone; that is, "expected future performance" should not be evaluated only on the basis of future budgets (i.e., historical results should not be excluded). In addition, competitive, operating, and financial risks related to each business or industry type should be considered in the determination of whether two operating segments have similar economic characteristics. If operating segments are located in different geographical areas, entities may need to evaluate factors such as economic and political conditions, currency risks, and foreign exchange control regulations.

Appendixes

Appendix A — Glossary of Standards and Other Literature

The standards and other literature below were cited or linked to in this publication.

AICPA Literature

Audit and Accounting Guide, *Assets Acquired to Be Used in Research and Development Activities*

FASB ASC References

For titles of *FASB Accounting Standards Codification* references, see Deloitte’s “Titles of Topics and Subtopics in the *FASB Accounting Standards Codification*.”

FASB Accounting Standards Updates and Other FASB Literature

See the FASB’s Web site for the titles of:

- [Accounting Standards Updates](#).
- [Proposed Accounting Standards Updates](#) (exposure drafts and public comment documents).
- [Pre-Codification literature](#) (Statements, Staff Positions, EITF Issues, and Topics).
- [Concepts Statements](#).

SEC Regulation S-K

Item 601, “Exhibits”

SEC Regulation S-X

Rule 3-05, “Financial Statements of Businesses Acquired or to Be Acquired”

Article 11, “Pro Forma Financial Information”

SEC Staff Accounting Bulletin

SAB Topic 13, “Revenue Recognition”

International Standards

See Deloitte’s [IAS Plus Web site](#) for the titles of:

- International Financial Reporting Standards.
- International Accounting Standards.
- [Exposure documents](#).

Appendix B — Abbreviations

Abbreviation	Description
AICPA	American Institute of Certified Public Accountants
ASC	FASB Accounting Standards Codification
ASU	FASB Accounting Standards Update
CEO	chief executive officer
CODM	chief operating decision maker
EBITDA	earnings before interest, taxes, depreciation, and amortization
EITF	Emerging Issues Task Force
FAF	Financial Accounting Foundation
FASB	Financial Accounting Standards Board
FDA	Food and Drug Administration
FIN	FASB Interpretation Number (superseded)
GAAP	generally accepted accounting principles
IAS	International Accounting Standard
IASB	International Accounting Standards Board
ICFR	internal control over financial reporting
IFRS	International Financial Reporting Standard

Abbreviation	Description
IPO	initial public offering
IPR&D	in-process research and development
LLC	limited liability company
M&A	merger and acquisition
MD&A	Management's Discussion and Analysis
MDET	medical device excise tax
PCAOB	Public Company Accounting Oversight Board
PCC	Private Company Council
PIR	post-implementation review
PTRS	probability of technical and regulatory success
Q&A	question and answer
R&D	research and development
SAB	SEC Staff Accounting Bulletin
SEC	Securities and Exchange Commission
SPE	special-purpose entity
TRG	transition resource group
VIE	variable interest entity

Appendix C — Other Resources

Deloitte Publications

Register to receive other Deloitte industry-related publications by going to www.deloitte.com/us/subscriptions. Publications pertaining to your selected industry (or industries), along with any other Deloitte publications or webcast invitations you choose, will be sent to you by e-mail.

Dbriefs

We also offer *Dbriefs* webcasts, which feature discussions by Deloitte professionals and industry specialists on critical issues that affect your business. Aimed at an executive-level audience, *Dbriefs* are designed to be timely, relevant, interactive, convenient, and supportive of your continuing professional education objectives. For more information about *Dbriefs*, please visit www.deloitte.com/us/dbriefs.

Technical Library and US GAAP Plus

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Updated every business day, Technical Library has an intuitive design and navigation system that, together with its powerful search features, enable users to quickly locate information anytime, from any computer. Technical Library subscribers also receive *Technically Speaking*, the weekly publication that highlights recent additions to the library. For more information, including subscription details and an online demonstration, visit www.deloitte.com/us/techlibrary.

In addition, be sure to visit [US GAAP Plus](#), our free Web site that features accounting news, information, and publications with a U.S. GAAP focus. It contains articles on FASB activities and updates to the *FASB Accounting Standards Codification*TM as well as developments of other U.S. and international standard setters and regulators, such as the PCAOB, AICPA, SEC, IASB, and IFRS Interpretations Committee. Check it out today!

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