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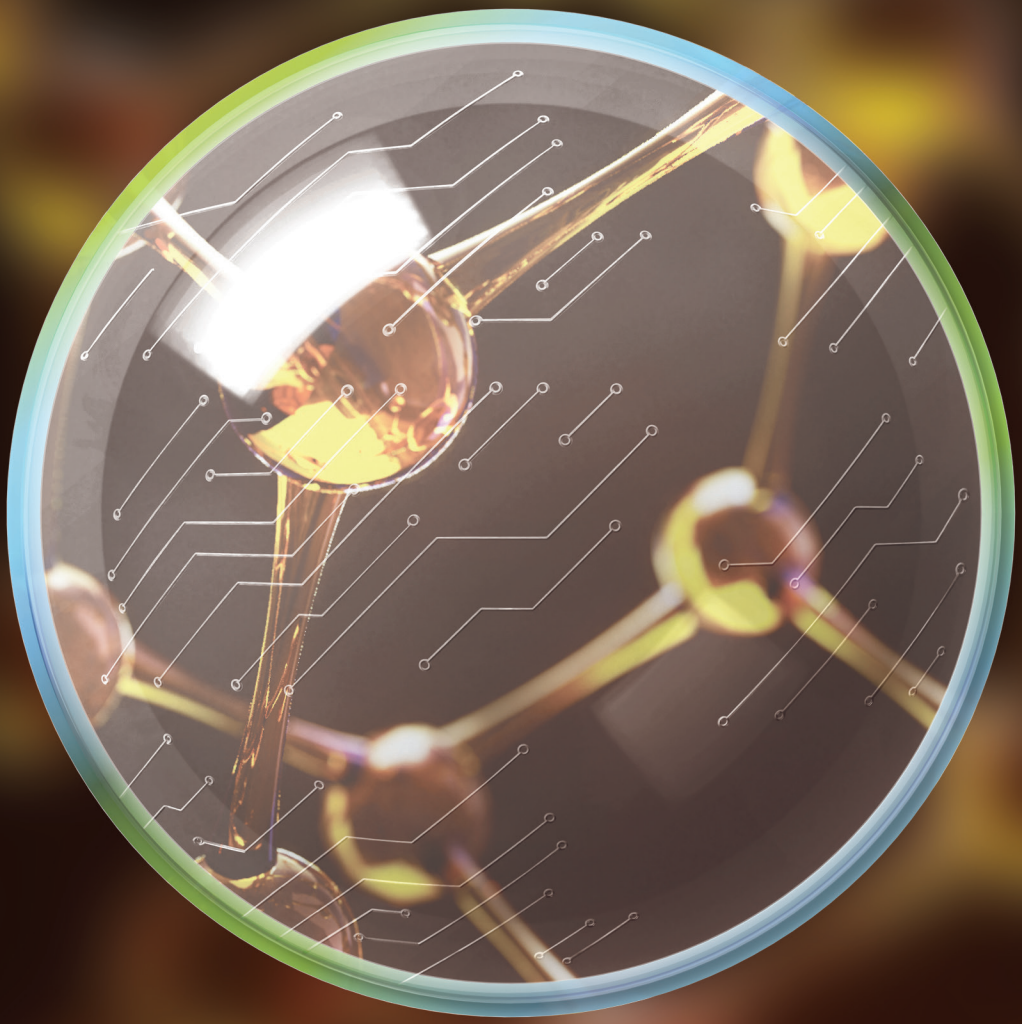

Life Sciences Industry Accounting Guide

Acquisitions and Divestitures

March 2024

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Preface

The life sciences ecosystem encompasses a wide array of entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and equipment manufacturers; and service companies such as drug distributors, contract research organizations (CROs), contract manufacturing organizations (CMOs), and health technology companies.

Finance and accounting professionals in the life sciences industry face complex issues and must exercise significant judgment in applying existing rules to matters such as research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The 2024 edition of Deloitte's *Life Sciences Industry Accounting Guide* (the "Guide") addresses these and other relevant topics affecting the industry this year. It includes interpretive guidance, illustrative examples, recent standard-setting and rulemaking developments (through March 8, 2024), and key differences between U.S. GAAP and IFRS® Accounting Standards. In addition, this Guide discusses (1) accounting and financial reporting considerations associated with the macroeconomic and geopolitical environment that apply specifically to the life sciences industry, (2) environmental, social, and governance (ESG) matters that have become topics of increased focus, and (3) the impact of the Inflation Reduction Act of 2022 (IRA).

Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used. Key changes made to this Guide since publication of the 2023 edition are summarized in Appendix D.

We hope the Guide is helpful in navigating the various accounting and reporting challenges that life sciences entities face. We encourage clients to contact their Deloitte team for additional information and assistance.

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Chapter 4 — Acquisitions and Divestitures

4.1 Introduction

Demand for health care services has grown worldwide, fueled by aging populations and burgeoning middle classes with expectations of higher-quality care. This, combined with a squeeze on funding, has driven the need for new business models. With public finances stretched, governments across the globe 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, and tap into alternative sources of innovation. As a result of these challenges, significant merger and acquisition (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 as a result of pricing pressures and patent expirations.

It is important for entities to correctly apply the guidance on accounting for M&A transactions because of the significantly different accounting outcomes that exist in this area of financial reporting. 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.

The sections below discuss some of the accounting issues related to acquisitions and divestitures that life sciences entities frequently encounter, as well as recent SEC comment letter feedback and FASB standard-setting developments related to this topic.

4.2 Industry Issues

4.2.1 Definition of a Business

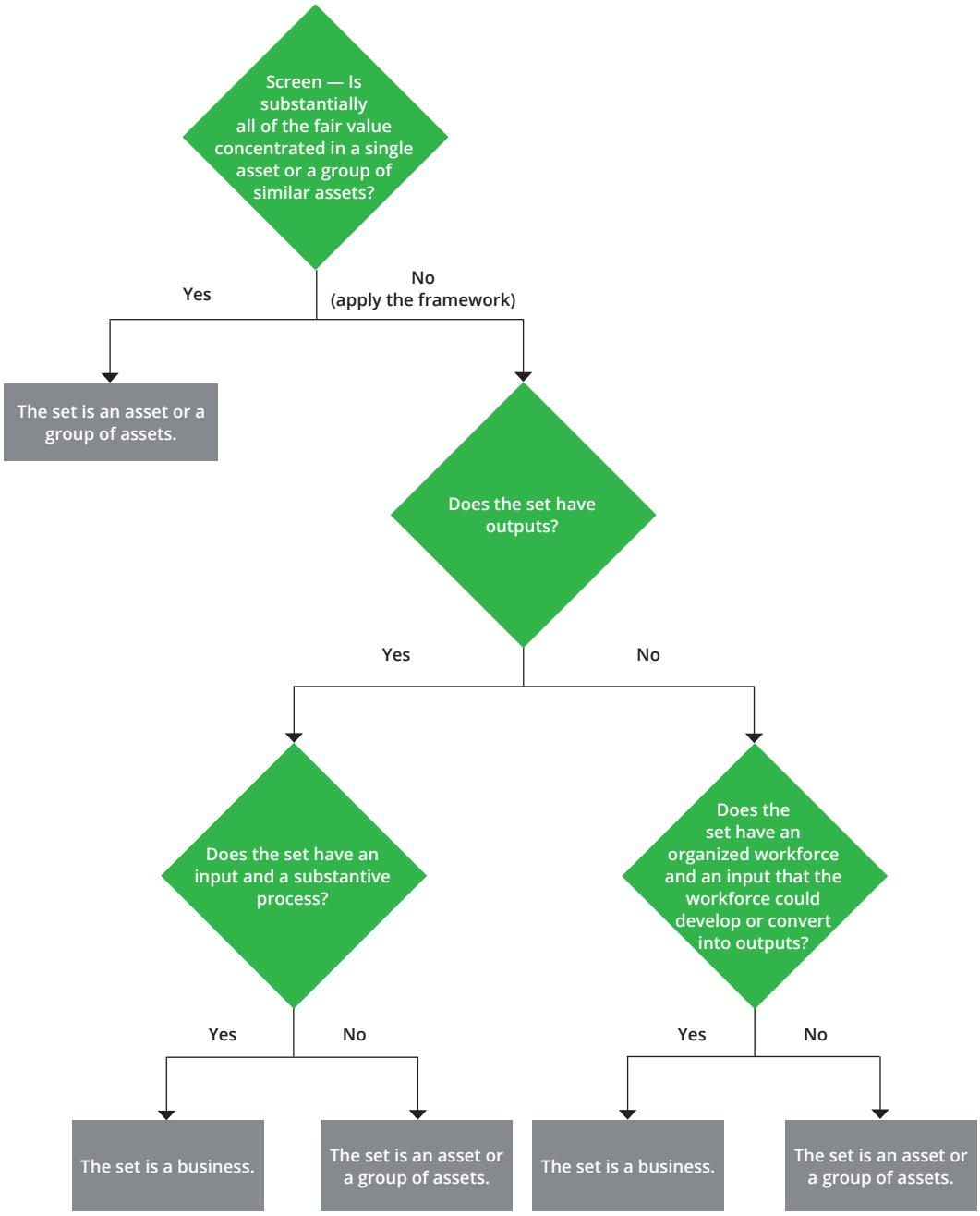
In recent years, M&A activity has increased in the life sciences industry as entities have continued to look for ways to expand their pipeline of products in development. An entity must use significant judgment in (1) evaluating whether a transaction represents the acquisition of a "business" as defined in ASC 805-10 and (2) accounting for transactions after that determination has been made.

ASC 805-10, ASC 805-20, and ASC 805-30 address the accounting for a business combination, which is defined in the ASC master glossary as "[a] transaction or other event in which an acquirer obtains control of one or more businesses." Typically, a business combination occurs when an entity purchases the equity interests or the net assets of one or more businesses in exchange for cash, equity interests of the acquirer, or other consideration. However, the definition of a business combination applies to more than just purchase transactions; it incorporates all transactions or events in which an entity or individual obtains control of a business.

If the acquisition does not meet the definition of a business combination, the entity must determine whether it should be accounted for as an asset acquisition under ASC 805-50. Distinguishing between the acquisition of a business and the acquisition of an asset or a group of assets is important because there are many differences between the accounting for each. Alternatively, if the assets acquired consist of primarily cash or investments, the substance of the transaction may be a capital transaction (a recapitalization) rather than a business combination or an asset acquisition.

To determine whether an acquisition should be accounted for as a business combination, an entity must evaluate whether the acquired set of assets and activities together meet the definition of a business in ASC 805.

An entity first uses a "screen" as prescribed by ASC 805-10-55-5A through 55-5C to assess 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. If the screen is not met, the entity must apply a "framework" for determining whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, the acquired set is a business. The decision tree below illustrates how to determine whether an acquisition represents a business combination or an asset acquisition.



SEC Considerations

SEC registrants are required to use the definition of a business in SEC Regulation S-X, Rule 11-01(d), when evaluating the requirements of SEC Regulation S-X, Rule 3-05, and SEC Regulation S-X, Article 11. The definition of a business in Rule 11-01(d) is different from the definition of a business in ASC 805-10.

Entities apply the definition of a business in ASC 805 in many areas of accounting, including acquisitions, disposals, reporting-unit determinations, and consolidation.

Some of the more common issues that life sciences entities have faced when applying the definition of a business are discussed below. For more information on any of these topics, see Deloitte's Roadmap *Business Combinations*.

4.2.1.1 Single or Similar Assets

As shown in the decision tree above, the definition of a business provides a practical "screen" to determine when a set is not a business. Once an entity has identified the acquired set, it then evaluates whether that set is not a business on the basis of the screen in ASC 805-10-55-5A through 55-5C. ASC 805-10-55-5A provides that under the screen, "[i]f 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 is not considered a business." An entity can evaluate whether the screen is met by applying the following steps:

- *Step 1* — Combine the identifiable assets into a single identifiable asset.
- *Step 2* — Combine the assets into similar assets.
- *Step 3* — Measure the fair value of the gross assets acquired.
- *Step 4* — Determine 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.

If a set is determined not to be a business under the screen, an entity does not need to evaluate the rest of the implementation guidance.

For purposes of applying steps 1 and 2 above, the FASB "decided that an entity should use the same unit of account when assessing the [screen] that it would use for identifying assets recognized in a business combination" and "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 . . . multiple versions of substantially the same asset type instead of precisely one asset").[1] The Board further noted 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."[2]

To avoid grouping too many assets together, ASC 805-10-55-5C indicates that "[w]hen evaluating whether assets are similar, an entity should consider the nature of each single identifiable asset and the risks associated with managing and creating outputs from the assets (that is, the risk characteristics)." Although the FASB does not define the term "similar" in ASC 805-10-55-5C, the guidance in that Codification paragraph provides examples of assets that cannot be considered similar:

a. A tangible asset and an intangible asset
b. Identifiable intangible assets in different major **intangible asset classes** (for example, customer-related intangibles, trademarks, and in-process research and development)
c. A financial asset and a nonfinancial asset
d. Different major classes of financial assets (for example, accounts receivable and marketable securities)
e. Different major classes of tangible assets (for example, inventory, manufacturing equipment, and automobiles)
f. Identifiable assets within the same major asset class that have significantly different risk characteristics. [Emphasis added]

ASC 805-10-55-65 through 55-68 illustrate how life sciences entities would apply the guidance discussed above.

[1] See paragraphs BC24 and BC28 of ASU 2017-01.
[2] See paragraph BC29 of ASU 2017-01.

ASC 805-10

Example 6: Illustrations of the Definition of a Business

Case B: Acquisition of a Drug Candidate

Scenario 1

55-65 Pharma Co. purchases from Biotech a legal entity that contains the rights to a Phase 3 (in the clinical research phase) 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. No employees, other assets, or other activities are transferred.

55-66 Pharma Co. first considers the guidance in paragraphs 805-10-55-5A through 55-5C. 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 qualitatively concludes that there is no fair value associated with the clinical research organization contract and the clinical manufacturing organization contract because the services are being provided at market rates and could be provided by multiple vendors in the marketplace. Therefore, all of the consideration in the transaction will 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.

Scenario 2

55-67 Pharma Co. purchases from Biotech a legal entity that contains the rights to a Phase 3 compound being developed to treat diabetes (Project 1) and a Phase 3 compound being developed to treat Alzheimer's disease (Project 2). Included with each 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 at-market clinical research organization contracts and at-market clinical manufacturing organization contracts associated with each project. Assume that Project 1 and Project 2 have equal fair value. No employees, other assets, or other activities are transferred.

55-68 Pharma Co. concludes that Project 1 and Project 2 are each separately identifiable intangible assets, both of which would be accounted for as a single asset in a business combination. Pharma Co. then considers whether Project 1 and Project 2 are similar assets. Pharma Co. notes that the nature of the assets is similar in that both Project 1 and Project 2 are in-process research and development assets in the same major asset class. However, Pharma Co. concludes that Project 1 and Project 2 have significantly different risks associated with creating outputs from each asset because each project has different risks associated with developing and marketing the compound to customers. The projects are intended to treat significantly different medical conditions, and each project has a significantly different potential customer base and expected market and regulatory risks associated with the assets. Thus, Pharma Co. concludes that substantially all of the fair value of the gross assets acquired is not concentrated in a single identifiable asset or group of similar identifiable assets and that it must further evaluate whether the set has the minimum requirements to be considered a business.

In some instances, an entity may be able to determine that the screen has been met solely on the basis of qualitative factors. For example, if the acquisition is limited to a single compound being studied to treat different indications that will be accounted for as a single unit of account, the screen has been met because the unit of account that the entity uses when assessing the screen should be the same as the unit of account that the entity determines when identifying assets recognized in a business combination. Similarly, if the acquisition includes a license for a drug candidate and an at-market contract that would have no fair value assigned to it, it may be clear that the screen has been met. By contrast, an entity may often be able to qualitatively determine that the screen has not been met if there is clearly significant value in assets that are not similar. Paragraph BC19 of ASU 2017-01 states, in part:

> In addition, an entity also could conclude that **the set is not a business** by assessing the guidance in paragraphs 805-10-55-5D through 55-6 and 805-10-55-8 through 55-9. The Board noted that **if the set is not a business**, an entity could choose to document its conclusion in the most cost-effective manner depending on its situation. [Emphasis added]

Therefore, entities may bypass the screen and proceed directly to the framework (see Section 4.2.1.2) as long as the set is determined not to be a business under the framework. However, entities may not bypass the screen and apply the framework to conclude that a set is a business since that determination may contradict the conclusion that would have been made by applying the screen.

Connecting the Dots

Life sciences entities may need to exercise significant judgment in performing a qualitative assessment to determine 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. For example, judgment may be required to determine whether:

- Compounds within the same major asset class possess "significantly different risk characteristics." For example, Scenario 2 of Example 6, Case B, describes two phase III compounds in different therapeutic specialties as possessing significantly different risk characteristics because each project (1) "has different risks associated with developing and marketing the compound to customers," (2) is "intended to treat significantly different medical conditions," and (3) "has a significantly different potential customer base and expected market and regulatory risks associated with the assets." In contrast, the acquisition of multiple approved generic products in the same therapeutic specialty might be considered to be similar assets because they require no further development, are marketed to the same customers, treat similar medical conditions, and may possess similar market and regulatory risks.
- Substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. For example, judgment may be necessary in the following circumstances:
    - When CRO contracts or CMO contracts are assumed, the reporting entity may have to use judgment to determine whether the services are being provided at market rates in such a manner that all of the consideration in a transaction would be allocated to an IPR&D project.
    - If an acquired product has received regulatory approval for a specific indication but certain other indications are still under development, the reporting entity may have to use judgment to determine whether substantially all of the fair value is concentrated in the approved indication or the unapproved indications, given that these assets may not be grouped because they represent different classes of intangible assets. Similar judgments would be required if an acquired product has received regulatory approval in one jurisdiction but not in another jurisdiction.

- When entities determine whether the "substantially all" threshold is met. The term "substantially all" is used throughout GAAP (e.g., in ASC 810, ASC 606, and ASC 842) and is generally interpreted to mean 90 percent or more. However, the FASB did not intend that entities treat the term as a bright line; thus, judgment must be applied in circumstances in which the quantitative result of the screen is close to 90 percent. In such cases, entities might consider other evidence to support their evaluation. For example, the following may be indicators that a set is a business:
  - The set includes many different types of assets (whereas a set with only a few assets may be more indicative of a group of assets).
  - The set includes an organized workforce or other substantive processes.
  - The set has outputs.
  - The set includes a significant amount of goodwill.
  - The set can operate independently on a stand-alone basis.

  If the quantitative result is close to 90 percent, the presence of one or more of these indicators might warrant a determination that the screen is not met. In that case, entities should apply the framework to determine whether the set is a business.

For more information on any of these topics — specifically, details of applying steps 1–4 and an illustration of the screen — see Section 2.4.2 of Deloitte's Roadmap *Business Combinations*.

4.2.1.2 Framework for Assessing Whether an Input and a Substantive Process Are Present

If the screen is not met, entities must determine whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. ASC 805-10-55 provides a framework for making that judgment. ASC 805-10-55-4(c) defines output as the "result of inputs and processes applied to those inputs that provide goods or services to customers, investment income (such as dividends or interest), or other revenues." Paragraph BC59 of ASU 2017-01 explains the FASB's basis for this definition:

> The Board decided to narrow the definition of outputs by aligning it with the ability to generate goods or services provided to customers. That is consistent with how outputs are discussed in Topic 606, which describes goods or services that are an output of the entity's ordinary activities. However, the Board noted that not all entities have revenues within the scope of Topic 606 and, therefore, decided to incorporate other types of revenues in the definition. For example, the Board decided to include the reference to investment income in the definition of outputs . . . to ensure that the purchase of an investment company can still qualify as a business combination.

The assessment of whether a set meets the definition of a business under the framework should be based on whether a market participant would be capable of conducting and managing the set as a business. Neither how the seller operated the set nor how the acquirer intends to operate the set is relevant in making the determination. For example, if an acquirer obtains a set with operations that are similar to its own, its plans to integrate the set into its operations and use its own processes to continue the production of outputs are not relevant in the determination of whether a substantive process was acquired.

ASU 2017-01 eliminated the need to assess whether a market participant is capable of replacing any missing elements to continue the production of outputs. Therefore, entities must now focus their analysis on what was acquired and no longer on whether a market participant could potentially replace missing elements.

The amendments in ASU 2017-01 provide criteria for entities to evaluate in determining whether a set has a substantive process. Those criteria vary depending on whether the set has outputs, as discussed below. In both instances, the set is a business if it includes, at a minimum, both an input and a substantive process that together significantly contribute to the ability to create outputs.

For more information on identifying the elements of a business, see Section 2.4.3.1 of Deloitte's Roadmap *Business Combinations*.

4.2.1.2.1 Sets Without Outputs

When outputs are not present (e.g., an early-stage company that has not generated revenues), an entity will need to apply more stringent criteria when determining whether a set has a substantive process. Paragraph BC38 of ASU 2017-01 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, as explained in paragraph BC39 of ASU 2017-01, for a set that does not have outputs to qualify as a business, it "must include 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 output." The existence of any employee does not mean that a set without outputs should be considered a business. ASC 805-10-55-5D 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 employees who form an organized workforce could develop (or are 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 of inputs that could be developed include technology, mineral interests, real estate, and in-process research and development.

ASC 805-10-55-70 through 55-72 illustrate the assessment that a life sciences entity would perform when a set has no outputs.

ASC 805-10

Example 6: Illustrations of the Definition of a Business

Case C: Acquisition of Biotech

55-70 Pharma Co. buys all of the outstanding shares of Biotech. Biotech's operations include research and development activities on several drug compounds that it is developing (in-process research and development projects). The in-process research and development projects are in different phases of the U.S. Food and Drug Administration approval process and would treat significantly different diseases. The set includes senior management and scientists that have the necessary skills, knowledge, or experience to perform research and development activities. In addition, Biotech has long-lived tangible assets such as a corporate headquarters, a research lab, and lab equipment. Biotech does not yet have a marketable product and, therefore, has not generated revenues. Assume that each research and development project has a significant amount of fair value.

ASC 805-10 (continued)

55-71 Pharma Co. first considers the guidance in paragraphs 805-10-55-5A through 55-5C. The identifiable assets in the set include multiple in-process research and development projects and tangible assets (the corporate headquarters, the research lab, and the lab equipment). Pharma Co. concludes that the in-process research and development projects are not similar assets because the projects have significantly different risks associated with managing the assets and creating the outputs (that is, because there are significantly different development risks in the different phases of development, market risks related to the different customer base, and potential markets for the compounds). In addition, Pharma Co. concludes that there is fair value associated with the acquired workforce because of the proprietary knowledge of and experience with Biotech's ongoing development projects and the potential for creation of new development projects that the workforce embodies. As such, Pharma Co. concludes that substantially all of the fair value of the gross assets acquired is not concentrated in a single identifiable asset or group of similar identifiable assets and that it must further evaluate whether the set has the minimum requirements to be considered a business.

55-72 Because the set does not have outputs, Pharma Co. evaluates the criteria in paragraph 805-10-55-5D to determine whether the set has both an input and a substantive process that together significantly contribute to the ability to create outputs. Pharma Co. concludes that the criteria 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 product that can be provided to a customer. Pharma Co. also determines that there is a more-than-insignificant amount of goodwill (including the fair value associated with the workforce), which is another indicator that the workforce is performing a critical process. Thus, the set includes both inputs and substantive processes and is a business.

For more information on analyzing sets without outputs, see Section 2.4.3.2 of Deloitte's Roadmap *Business Combinations*.

4.2.1.2.2 Sets With Outputs

Paragraph BC51 of ASU 2017-01 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 805-10-55-5E indicates that the set would include a substantive process if any of the following criteria are met:

a. Employees that form 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. An acquired contract that provides access to 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. An entity should assess the substance of an acquired contract and whether it has effectively acquired an organized workforce that performs a substantive process (for example, considering the duration and the renewal terms of the contract).

c. The acquired process (or group of processes) when applied to an acquired input or inputs significantly 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.

d. The acquired process (or group of processes) when applied to an acquired input or inputs significantly contributes to the ability to continue producing outputs and is considered unique or scarce.

As indicated by that guidance, an organized workforce "must have 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 determination of whether an organized workforce is performing a critical process requires judgment and varies from transaction to transaction.

A substantive process may also be present without an organized workforce when a set has outputs. For example, a set may have automated processes through acquired technology or infrastructure (e.g., automated technology, or a manufacturing or production line). In accordance with ASC 805-10-55-5E, for an automated process to be considered substantive, (1) it must significantly contribute "to the ability to continue producing outputs" when applied to an input or inputs and (2) the acquirer cannot have the ability to replace it "without significant cost, effort, or delay in the ability to continue producing outputs," or it must be "unique or scarce."

Further, ASC 805-10-55-5F states the following:

ASC 805-10

55-5F If a set has outputs, 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 in paragraph 805-10-55-5E of whether a process has been acquired.

ASC 805-10-55-82 through 55-84 illustrate the application of the above guidance to arrangements that involve licensing and distribution rights, which are common among life sciences entities.

ASC 805-10

Example 6: Illustrations of the Definition of a Business

Case F: License of Distribution Rights

55-82 Company A is a distributor of food and beverages. Company A enters into an agreement to sublicense the Latin American distribution rights of Yogurt Brand F to Company B, whereby Company B will distribute Yogurt Brand F in Latin America. As part of the agreement, Company A transfers the existing customer contracts in Latin America to Company B and an at-market supply contract with the producer of Yogurt Brand F. Company A retains all of its employees and distribution capabilities.

55-83 Company B first considers the guidance in paragraphs 805-10-55-5A through 55-5C. The identifiable assets that could be recognized in a business combination include the license to distribute Yogurt Brand F, customer contracts, and the supply agreement. Company B concludes that the license and customer contracts will have fair value assigned to them. Company B concludes that neither asset represents substantially all of the fair value of the gross assets. Company B then considers whether the license and customer contracts are a group of similar intangible assets. Because the license and customer contracts are in different major classes of identifiable intangible assets, they are not considered similar assets. Therefore, substantially all of the fair value of the gross assets acquired is not concentrated in a single identifiable asset or group of similar identifiable assets, and Company B must evaluate whether the set has both an input and a substantive process.

ASC 805-10 (continued)

55-84 The set has outputs through the continuation of revenues with customers in Latin America. As such, Company B must evaluate the criteria in paragraph 805-10-55-5E to determine whether the set includes an input and a substantive process that together significantly contribute to the ability to create outputs. Company B considers whether the acquired contracts are providing access to an organized workforce that performs a substantive process. However, because the contracts are not providing a service that applies a process to another acquired input, Company B concludes that the substance of the contracts are only that of acquiring inputs. The set is not a business because:

a. It does not include an organized workforce that could meet the criteria in paragraph 805-10-55-5E(a) through (b).

b. There are no acquired processes that could meet the criteria in paragraph 805-10-55-5E(c) through (d).

c. It does not include both an input and a substantive process.

For more information on analyzing sets with outputs, see Section 2.4.3.3 of Deloitte's Roadmap *Business Combinations*.

Connecting the Dots

When the set has outputs, the presence of an acquired contract that provides access to an organized workforce could meet the less stringent criteria for determining that a substantive process has been acquired and therefore result in a conclusion that the set represents a business. It is important to note that the assessment of an acquired contract is relevant only if the set has outputs. In the life sciences industry, transactions may be limited to the acquisition of (1) an early-stage product candidate or (2) an entity that does not have outputs but may include an acquired service provider contract (e.g., with a CRO or a CMO). In such circumstances, the presence of the acquired contract cannot represent a substantive process. Instead, for the acquired set to represent a business, it would need to include employees who form an organized workforce and an input that the workforce could develop or convert into outputs.

4.2.1.3 SEC Considerations

A registrant must also consider certain SEC reporting requirements when it acquires an asset or a group of assets. For instance, the registrant must separately evaluate whether the asset or group of assets meets the definition of a business for SEC reporting purposes under SEC Regulation S-X, Rule 11-01(d), since this definition differs from the U.S. GAAP definition of a business under ASC 805-10. For more information about the SEC's reporting requirements for an asset acquisition, see Section C.5 of Deloitte's Roadmap *Business Combinations*.

4.2.2 Asset Acquisitions

In applying the framework in ASC 805, entities must account for transactions that do not meet the definition of a business as asset acquisitions. An asset acquisition is accounted for in accordance with the "Acquisition of Assets Rather Than a Business" subsections of ASC 805-50 by using a cost accumulation model. In such a model, the cost of the acquisition, including certain transaction costs, is allocated to the assets acquired on the basis of relative fair values. By contrast, a business combination is accounted for by using a fair value model under which (1) the assets and liabilities are generally recognized at their fair values and (2) the difference between the consideration transferred, excluding acquisition-related costs, and the fair values of the assets and liabilities is recognized as goodwill. As a result, there are significant differences between the accounting for an asset acquisition and the accounting for a business combination, as summarized below.

Issue	Accounting in a Business Combination	Accounting in an Asset Acquisition
General principle	Fair value model: assets and liabilities are recognized at fair value, with certain exceptions.	Cost accumulation model: the cost of the acquisition, including certain transaction costs, is allocated to the assets acquired on the basis of relative fair values, with some exceptions. This allocation results in the recognition of those assets at other than their fair values.
Scope	Acquisition of a business as defined in ASC 805-10.	Acquisition of an asset or a group of assets (and liabilities) that does not meet the definition of a business in ASC 805-10.
Acquisition-related costs or transaction costs	Acquisition-related costs are expensed as incurred, except for costs of issuing debt and equity securities, which are accounted for under other GAAP.	Direct and incremental costs are included in the cost of the acquisition, except for costs of issuing debt and equity securities, which are accounted for under other GAAP. Indirect costs are expensed as incurred.
Contingent consideration	Recognized at fair value and classified as a liability, equity, or an asset on the acquisition date on the basis of the terms of the arrangement. Subsequently, any changes in the fair value of contingent consideration classified as a liability or as an asset are recognized in earnings until settled.	Contingent consideration that is accounted for as a derivative is recognized at fair value under ASC 815. Otherwise, such consideration generally is recognized under ASC 450 when it becomes probable and reasonably estimable or when the contingency is resolved by analogy to FASB Statement 141.
Goodwill	If the sum of the consideration transferred, the fair value of any noncontrolling interests, and the fair value of any previously held interests exceeds the sum of the identifiable assets acquired and liabilities assumed, goodwill is recognized as the amount of the excess.	Goodwill is not recognized. Instead, any excess of the cost of the acquisition over the fair value of the net assets acquired is allocated to certain assets on the basis of relative fair values.
Gain from bargain purchase	Recognized in earnings on the acquisition date.	Generally not recognized in earnings. Instead, any excess of the fair value of the net assets acquired over the cost of the acquisition is typically allocated to certain assets on the basis of relative fair values.
Contingencies	Measured at fair value, if determinable; otherwise, measured at their estimated amounts if probable and reasonably estimable. If such assets or liabilities cannot be measured during the measurement period, they are accounted for separately from the business combination in accordance with ASC 450.	Accounted for in accordance with ASC 450 on the acquisition date and subsequently. Loss contingencies are recognized when they are probable and reasonably estimable. Gain contingencies are recognized when realized and are thus not recognizable in an asset acquisition.
Intangible assets	Recognized at fair value if they are identifiable (i.e., if they are separable or arise from contractual rights).	Finite-lived intangible assets recognized on the basis of relative fair value under ASC 350-10 if they meet the asset recognition criteria in FASB Concepts Statement 5. Indefinite-lived intangible assets are recognized at amounts that do not exceed fair value.

(Table continued)

Issue	Accounting in a Business Combination	Accounting in an Asset Acquisition
Assembled workforce	Not recognized because it is presumed not to be identifiable.	Recognized because it is presumed to meet the asset recognition criteria in FASB Concepts Statement 5.
IPR&D	Measured at fair value and recognized as an indefinite-lived intangible asset until completion or abandonment of the related project, then reclassified as a finite-lived intangible asset and amortized.	Expensed under ASC 730 unless the IPR&D has an alternative future use.
Deferred taxes	Generally recognized for most temporary book/tax differences related to assets acquired and liabilities assumed under ASC 740.	Generally recognized for temporary book/tax differences in an asset acquisition by using the simultaneous equations method in accordance with ASC 740.
Lease classification	Under ASC 840-10-25-27, the acquirer retains the acquiree's previous lease classification "unless the provisions of the lease are modified as indicated in paragraph 840-10-35-5." Under ASC 842-10-55-11, the acquirer retains the acquiree's previous lease classification "unless there is a lease modification and that modification is not accounted for as a separate contract in accordance with paragraph 842-10-25-8."	ASC 805-50 does not provide guidance on an entity's classification of a lease acquired in an asset acquisition.
Measurement period	In accordance with ASC 805-10-25-13, the acquirer reports provisional amounts for the items for which the accounting "is incomplete by the end of the reporting period in which the combination occurs" and is allowed up to one year to adjust those provisional amounts. This time frame is referred to as the measurement period.	ASC 805-50 does not address a measurement period in the context of an asset acquisition.

See Appendix C of Deloitte's Roadmap *Business Combinations* for detailed accounting considerations related to asset acquisitions, including the scope of ASC 805-50 and scope exceptions for VIEs.

4.2.2.1 Cost of the Acquisition

An asset acquisition is an exchange transaction that triggers the acquiring entity's initial recognition of the assets acquired or liabilities assumed and the derecognition of any consideration given on the date of the acquisition. ASC 805-50-30-2 provides the general principle for measuring the cost of an asset acquisition and specifies, in part, that an asset acquisition should be recognized at cost, which is measured on the basis of either (1) "the fair value of the consideration given" or (2) "the fair value of the assets (or net assets) acquired, whichever is more clearly evident and, thus, more reliably measurable."

In many asset acquisitions, the consideration is cash and, therefore, determining the cost of the acquisition is relatively straightforward. If the consideration given is wholly in the form of cash, the cost of the asset acquisition is measured on the basis of the cash paid plus the direct transaction costs incurred to effect the acquisition.

In some asset acquisitions, part or all of the consideration given may consist of noncash assets, equity interests, or liabilities incurred by the seller (e.g., contingent consideration). When consideration other than cash is used, entities should first determine whether the exchange is within the scope of other GAAP and, if so, apply the applicable standard's guidance. See Section C.2 of Deloitte's Roadmap *Business Combinations* for types of noncash consideration and the U.S. GAAP that entities should apply to measure the cost of the assets acquired. Of these types of noncash consideration, contingent consideration is very common in the life sciences industry (see Section 4.2.2.2 for further discussion).

In instances in which the form of the consideration given is the acquiring entity's equity instruments, we are aware of two views in practice regarding the date on which the acquiring entity should measure such equity instruments in an asset acquisition. The first view is that the guidance in ASC 805-50-25-1 requires the acquiring entity's equity instruments to be measured on the date of the asset acquisition. The second view is that the issuance of shares as consideration in an asset acquisition represents a share-based payment to nonemployees in exchange for goods. Under that view, the acquiring entity would apply ASC 718 when measuring the equity instruments it issued as consideration in an asset acquisition. Applying ASC 718 may result in a measurement date (i.e., the grant date) that precedes the acquisition date for the shares issued. In addition, to the extent that an entity applies the guidance in ASC 805, it should consider the guidance in ASC 815-10, ASC 480, and ASC 815-40 in determining whether to classify the shares to be issued as part of the asset acquisition as a liability or as equity. However, an entity that applies the ASC 718 framework should consider the guidance in ASC 718-10-25-9, which may result in a different classification outcome.

At the FASB's March 3, 2021, agenda prioritization meeting, the Board decided not to add an agenda item related to the clarification of guidance on certain asset acquisition and nonemployee share-based payment transactions. However, on the basis of the discussion at that meeting, we believe that either view is acceptable provided that entities apply a consistent view. Given the complexities associated with such transactions, entities should consult with their accounting advisers when dealing with these matters.

4.2.2.2 Contingent Consideration

The ASC master glossary defines contingent consideration as follows:

> Usually an obligation of the acquirer to transfer additional assets or equity interests to the former owners of an acquiree as part of the exchange for control of the acquiree if specified future events occur or conditions are met. However, contingent consideration also may give the acquirer the right to the return of previously transferred consideration if specified conditions are met.

While that definition applies to contingent consideration issued in a business combination, contingent consideration may also be issued in an asset acquisition. The acquiring entity should assess the terms of the transaction to determine whether consideration payable at a future date is contingent consideration or seller financing. If the payment depends on the occurrence of a specified future event or the meeting of a condition and the event or condition is substantive, the additional consideration should be accounted for as contingent consideration. If the additional payment depends only on the passage of time or is based on a future event or the meeting of a condition that is not substantive, the arrangement should be accounted for as seller financing.

ASC 805-50 states that any liabilities incurred by the acquiring entity are part of the cost of the asset acquisition, but it does not provide any specific guidance on accounting for contingent consideration in an asset acquisition. However, in EITF Issue 09-2, the Task Force addressed contingent consideration in an asset acquisition. While a final consensus was not reached, the minutes from the September 9–10, 2009, EITF meeting state that "the Task Force reached a consensus-for-exposure that contingent

consideration in an asset acquisition shall be accounted for in accordance with existing U.S. GAAP." The following examples (not all-inclusive) were provided:

- "[I]f the contingent consideration meets the definition of a derivative, Topic 815 (formerly Statement 133) would require that it be recognized at fair value."
- "Topic 450 (formerly Statement 5) may require recognition of the contingent consideration if it is probable that a liability has been incurred and the amount of that liability can be reasonably estimated."
- "Subtopic 323-10 (formerly Issue 08-6) may require the recognition of the contingent consideration if it relates to the acquisition of an investment that is accounted for under the equity method."

Another example would be if the contingent consideration arrangement is settleable in, or is indexed to, the acquirer's equity shares, the acquirer may be required to measure the contingent consideration arrangement at its acquisition-date fair value in accordance with the guidance in ASC 480 or ASC 815. See Deloitte's Roadmap *Contracts on an Entity's Own Equity* for more information.

The minutes also state that when contingent consideration related to an asset acquisition is recognized at inception, "such [an] amount would be included in the initial measurement of the cost of the acquired assets. . . . However, if the contingent consideration arrangement is a derivative, changes in the carrying value of a derivative instrument subsequent to inception [would be recognized in accordance with ASC 815 and] would not be recognized as part of the cost of the asset."

ASC 815-10-15-83 defines a derivative instrument as follows:

ASC 815-10

15-83 A derivative instrument is a financial instrument or other contract with all of the following characteristics:

a. Underlying, notional amount, payment provision. The contract has both of the following terms, which determine the amount of the settlement or settlements, and, in some cases, whether or not a settlement is required:
   1. One or more underlyings
   2. One or more notional amounts or payment provisions or both.

b. Initial net investment. The contract requires no initial net investment or an initial net investment that is smaller than would be required for other types of contracts that would be expected to have a similar response to changes in market factors.

c. Net settlement. The contract can be settled net by any of the following means:
   1. Its terms implicitly or explicitly require or permit net settlement.
   2. It can readily be settled net by a means outside the contract.
   3. It provides for delivery of an asset that puts the recipient in a position not substantially different from net settlement.

In the life sciences industry, companies often enter into arrangements that include required cash payments associated with various milestones (e.g., development milestones, regulatory milestones, sales-based milestones). Many of these contingent arrangements may meet all of the characteristics of a derivative in that they have an underlying (i.e., the occurrence of certain events), a payment provision (i.e., fixed cash payment if certain events occur), and no initial net investment. Further, we believe that

the payments made in accordance with the behavior of the underlying are contractually net settleable if the terms of the agreements call for the payment of cash upon the occurrence of an event.[3]

While certain contingent consideration may meet all of the characteristics of a derivative, further assessment is required to inform the accounting. ASC 815-10-15-13 lists the types of contracts that are not subject to ASC 815-10 **even if** they have the characteristics of a derivative instrument. Among those types of contracts are "[c]ertain contracts that are not traded on an exchange."

Since the milestone payment arrangements described herein are not traded on an exchange, further evaluation is required for entities to determine whether a scope exception for such contracts is applicable. ASC 815-10-15-59 provides that contracts that are not exchange-traded are not subject to the requirements of ASC 815-10 if the underlying on which the settlement is based qualifies for one of four scope exceptions, the following two of which are commonly observed in practice in the life sciences industry:

- *ASC 815-10-15-59(b)* — Provides a scope exception for non-exchange-traded contracts with an underlying that is the "price or value of a nonfinancial asset of one of the parties to the contract provided that the asset is not readily convertible to cash." This scope exception applies only if both of the following conditions exist:
    - "The nonfinancial assets are unique."
    - "The nonfinancial asset related to the underlying is owned by the party that would not benefit under the contract from an increase in the fair value of the nonfinancial asset."

  For example, suppose that Company X enters into a contract to acquire IP (e.g., a license) from Company Y that represents a development platform designed to provide drug developers with a revolutionary approach to delivering a particular medicine (the "Product"). In connection with the acquisition of the IP, X is required to make milestone payments to Y related to clinical development milestones and subsequent product approvals that leverage the acquired platform in the development of the Product.

  The underlying on which the settlement is based is related to a nonfinancial asset — the acquired IP. The milestone payments become due after clinical development milestones and the successful Product approvals that leverage the acquired IP. Although there may or may not be an asset recorded on the balance sheet for each milestone payment (i.e., all of the payments may not qualify for capitalization), the achievement of the milestones is highly correlated to the fair value of the IP (i.e., once the milestones are achieved, the fair value of the IP increases).

  In this example, the acquired IP is considered a unique nonfinancial asset because any products that leverage this technology represent complex, scientifically engineered therapies supported by a one-of-a-kind platform that are not readily interchangeable with similar products in the market (i.e., the products are not "assembly line widgets"). Further, the product rights are owned by X, and X would not benefit under the terms of the contract from an increase in the fair value of the acquired IP. This is because the *contract*, for purposes of evaluating whether the scope exception in ASC 815-10-15-59(b) applies, is the milestone payment arrangement between X and Y. Since X can only make a payment to the counterparty under this arrangement, it cannot benefit under the contract. While X does benefit from the achievement of reaching clinical development milestones and the ultimate regulatory approval of new product offerings that leverage the acquired IP, the benefit to X arises from owning the underlying nonfinancial asset and not from the contract that results in milestone payments to Y.

[3] ASC 815-10-15-100 states, in part, that in a net settlement under contract terms, "neither party is required to deliver an asset that is associated with the underlying and that has a principal amount, stated amount, face value, number of shares, or other denomination that is equal to the notional amount (or the notional amount plus a premium or minus a discount). . . . Net settlement may be made in cash or by delivery of any other asset . . . , whether or not that asset is readily convertible to cash."

We would most likely not reach the same conclusion regarding the applicability of the scope exception if the above fact pattern applied to an R&D funding arrangement, as opposed to the acquisition of a license.

- *ASC 815-10-15-59(d)* — Provides a scope exception for non-exchange-traded contracts in which settlement is based on "[s]pecified volumes of sales or service revenues of one of the parties to the contract." The guidance states that "[t]his scope exception does not apply to contracts based on changes in sales or revenues due to changes in market prices."

  Contingent consideration arrangements in the life sciences industry commonly include sales-based milestones that obligate the acquirer to remit a stated amount corresponding to a predetermined sales volume. In these cases, the underlying on which the settlement is based is a specified volume of sales (as opposed to changes in sales based only on changes in market prices).

Upon concluding that the contingent consideration under a milestone payment arrangement meets one of the scope exceptions in ASC 815, an entity would proceed with accounting for the contingent consideration in accordance with its accounting policy (see Connecting the Dots below for a discussion of accounting policy alternatives). If the entity is required to account for the contingent consideration as a derivative, the fair value of the contingent consideration recognized would be included in the consideration transferred and would become part of the cost basis of the asset(s) acquired.

Connecting the Dots

We understand that in the absence of a final consensus on EITF Issue 09-2, diversity in practice exists for contingent consideration that is outside the scope of ASC 815 and ASC 323-10 (i.e., contingent consideration that is neither a derivative nor related to the acquisition of an equity method investment). While some practitioners refer to the guidance in ASC 450, others continue to analogize to the guidance in FASB Statement 141, paragraph 27, which states that "contingent consideration usually should be recorded when the contingency is resolved and consideration is issued or becomes issuable." Given the lack of authoritative guidance, we believe that either approach would be acceptable. Regardless of which approach is applied, because of the inherent uncertainties associated with the regulatory approval process, contingent consideration based on regulatory approval is generally not considered probable until the contingency is met.

The example below illustrates how an entity may account for a sales-based milestone payment in an asset purchase agreement.

Example 4-1

Company A enters into an asset purchase agreement with Company B to acquire IP rights to an approved pharmaceutical product in exchange for an up-front cash payment of $10,000 and an additional cash payment of $20,000 upon achieving $200,000 in net sales for the product (i.e., a sales-based milestone payment). No other assets or liabilities are exchanged as part of the asset purchase agreement. Company A determines the following:

- The acquisition of the product does not meet the definition a business under ASC 805 and therefore should be accounted for as an asset acquisition under ASC 805-50.
- The additional cash payment of $20,000 represents contingent consideration as defined in ASC 805-10-20 (i.e., the payment does not depend solely on the passage of time).
- The contingent consideration meets the definition of a derivative instrument in ASC 815-10-15-83. However, the contingent consideration is subject to ASC 815-10-15-59's scope exception to the guidance on derivative accounting.
- Company A has not previously established an accounting policy for recognizing contingent consideration payments associated with an asset acquisition.

To account for the asset acquisition, A capitalizes the up-front cash payment of $10,000 as an intangible asset because the IP rights are related to an approved product and the cost is recoverable on the basis of expected future cash flows. To account for the contingent consideration of $20,000, A makes an accounting policy election to account for contingent consideration in an asset acquisition under the guidance in ASC 450. That is, A will recognize the contingent consideration when (1) it is probable that the sales-based milestone will be achieved and (2) the contingent consideration is reasonably estimable.

In Example 4-1, A makes an accounting policy election to account for contingent consideration in an asset acquisition under the guidance in ASC 450. However, A could make an alternative policy election to account for contingent consideration in an asset acquisition under the guidance in FASB Statement 141, paragraph 27. Under this guidance, A would recognize contingent consideration in an asset acquisition when the contingency is resolved and the amount becomes payable (i.e., when the $200,000 sales milestone is achieved and the $20,000 cash payment is due). Company A should consistently apply its accounting policy election to future transactions.

Contingent consideration that is recognized at a later date (i.e., not recognized as of the acquisition date) should be capitalized as part of the cost of the assets acquired and allocated to increase the eligible assets on a relative fair value basis. (However, if the contingent consideration is related to IPR&D assets with no alternative future use, the amount of the contingent payment should be expensed.) Similarly, we believe that if the acquiring entity receives a payment from the seller for the return of previously transferred consideration (i.e., a contingent consideration asset), the entity should allocate that amount to reduce the eligible assets on a relative fair value basis.

Diversity in practice has been observed regarding how entities that recognize contingent consideration at a later date make the resulting adjustments to amortizable or depreciable identifiable assets (e.g., PP&E or a finite-lived intangible asset). Some entities have recognized a cumulative catch-up in the amortization or depreciation of the asset as if the amount had been capitalized as of the date of acquisition, and other entities have accounted for the adjustment prospectively in a manner similar to a change in estimate. In the absence of guidance, we believe that either approach is acceptable.

4.2.2.2.1 Contingent Consideration When the Fair Value of the Assets Acquired Exceeds the Initial Consideration Paid

We believe that if the fair value of the assets acquired exceeds the initial consideration paid as of the date of acquisition, but the arrangement includes contingent consideration, an entity may either apply the guidance described in Section 4.2.2.2 or analogize to the guidance in ASC 323-10-25-2A and ASC 323-10-30-2B on recognizing contingent consideration in the acquisition of an equity method investment (unless the contingent consideration arrangement meets the definition of a derivative, in which case it would be accounted for in accordance with ASC 815).

Like acquisitions of equity method investments, asset acquisitions are accounted for under a cost accumulation model. Accordingly, 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 that does not meet the definition of a derivative, the entity could 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 consideration paid.

Once recognized, the contingent consideration liability is not derecognized until the contingency is resolved or the consideration is issued. In accordance with the requirements of ASC 323-10-35-14A for equity method investments, the entity recognizes "any excess of the fair value 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 (i.e., the amount is allocated to increase the eligible assets on a relative fair value basis). Further, "[i]f the amount initially recognized as a liability exceeds the fair value of the [contingent] consideration issued or issuable," the entity recognizes that amount as a reduction of the cost of the asset acquisition (i.e., the amount is allocated to reduce the eligible assets on a relative fair value basis). See Section 4.2.2.5.4 for additional accounting considerations when the fair value of an asset group that represents IPR&D exceeds its cost and the acquisition involves contingent consideration.

Note that before an entity elects to apply the guidance in ASC 323-10 by analogy, it should consider (1) consulting with its accounting advisers and (2) discussing its approach with the SEC staff on a prefiling basis (if the entity is an SEC registrant).

4.2.2.3 Consideration in the Form of Nonmonetary Assets or Nonfinancial Assets (After Adoption of ASC 606 and ASC 610-20)

In recent years, some life sciences companies have entered into transactions to swap products with other life sciences companies to build critical mass in a specialty such as oncology or diabetes care.

While ASC 805-50 provides a general principle for measuring the cost of an asset acquisition, it refers to other GAAP if the noncash consideration is in the form of nonmonetary assets, nonfinancial assets, or in-substance nonfinancial assets. ASC 805-50-30-1 states, in part:

> For transactions involving nonmonetary consideration within the scope of Topic 845, an acquirer must first determine if any of the conditions in paragraph 845-10-30-3 apply. If the consideration given is nonfinancial assets or in substance nonfinancial assets within the scope of Subtopic 610-20 on gains and losses from the derecognition of nonfinancial assets, the assets acquired shall be treated as noncash consideration and any gain or loss shall be recognized in accordance with Subtopic 610-20.

Therefore, an entity begins its evaluation by determining whether the transaction meets any of the exceptions in ASC 845-10-30-3, which states:

> A nonmonetary exchange shall be measured based on the recorded amount (after reduction, if appropriate, for an indicated impairment of value as discussed in paragraph 360-10-40-4) of the nonmonetary asset(s) relinquished, and not on the fair values of the exchanged assets, if any of the following conditions apply:
>
> a. The fair value of neither the asset(s) received nor the asset(s) relinquished is determinable within reasonable limits.
>
> b. The transaction is an exchange of a product or property held for sale in the ordinary course of business for a product or property to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange.
>
> c. The transaction lacks commercial substance (see [ASC 845-10-30-4]).

We believe that it is unlikely that the condition in ASC 845-10-30-3(a) would be met because the fair value of either or both of the assets that were surrendered or the assets (or net assets) that were received should be determinable "within reasonable limits." Entities therefore should consider whether the transaction (1) represents "an exchange of a product or property held for sale in the ordinary course of business for a product or property to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange" or (2) lacks commercial substance. Entities should consider the guidance in ASC 845-10 in making that determination. If the transaction meets any of the three conditions in ASC 845-10-30-3, the acquiring entity accounts for the transaction on the basis of the carrying amount of the nonmonetary asset given and recognizes no gain or loss (other than for impairment, if necessary).

If the transaction does not meet any of the three conditions in ASC 845-10-30-3, we believe that entities should then consider whether the consideration given is in the form of nonfinancial assets (or in-substance nonfinancial assets). If so, the transaction is within the scope of ASC 610-20 if the transaction is with a noncustomer (or ASC 606 if the transaction is with a customer).

ASC 805-50-30-1 states, in part, that "[i]f the consideration given is nonfinancial assets or in substance nonfinancial assets within the scope of Subtopic 610-20 on gains and losses from the derecognition of nonfinancial assets, the assets acquired shall be treated as noncash consideration and any gain or loss shall be recognized in accordance with Subtopic 610-20." Therefore, regardless of whether the assets are being received from a customer or a noncustomer, an entity applies the guidance in ASC 606-10-32-21 and 32-22 for measuring noncash consideration. However, the guidance an entity applies for recognizing the gain or loss depends on whether the assets are being received from a noncustomer or a customer. If the assets are received from a noncustomer, the entity applies the guidance in ASC 610-20 for recognizing the gain or loss, whereas if the assets are received from a customer in exchange for goods or services and the transaction is within the scope of ASC 606, the entity applies the guidance in ASC 606 on recognizing the gain or loss.

ASC 610-20-15-2 indicates that "[n]onfinancial assets . . . include intangible assets, land, buildings, or materials and supplies and may have a zero carrying value." ASC 610-20-15-2 also indicates that, subject to certain exceptions described in ASC 610-20-15-4, the guidance in ASC 610-20 "applies to gains or losses recognized upon the derecognition of nonfinancial assets and in substance nonfinancial assets." ASC 610-20-15-5 describes an in-substance nonfinancial asset as follows:

> [A] financial asset (for example, a receivable) promised to a counterparty in a contract if substantially all of the fair value of the assets (recognized and unrecognized) that are promised to the counterparty in the contract is concentrated in nonfinancial assets. If substantially all of the fair value of the assets that are promised to a counterparty in a contract is concentrated in nonfinancial assets, then all of the financial assets promised to the counterparty in the contract are in substance nonfinancial assets. For purposes of this evaluation, when a contract includes the transfer of ownership interests in one or more consolidated subsidiaries that is not a business, an entity shall evaluate the underlying assets in those subsidiaries.

According to ASC 610-20-15-4(g), ASC 610-20 does not apply to a "nonmonetary transaction within the scope of Topic 845 on nonmonetary transactions." Therefore, if the assets are not nonfinancial assets (or in-substance nonfinancial assets), entities should consider whether the assets are nonmonetary assets. The ASC master glossary defines nonmonetary assets and liabilities as "assets and liabilities other than monetary ones" and notes that examples of such assets and liabilities include "inventories; investments in common stocks; property, plant, and equipment; and liabilities for rent collected in advance." We believe that it may be challenging for entities to determine whether an exchange of noncash assets is an exchange of nonfinancial assets within the scope of ASC 610-20 or a nonmonetary exchange within the scope of ASC 845, and there is no additional guidance in U.S. GAAP on how to make this determination. However, we believe that the definition of nonmonetary assets and liabilities is broader than the definitions of nonfinancial assets and in-substance nonfinancial assets.

Entities were required to adopt ASC 610-20 at the same time that they adopted ASC 606. See Chapter 17 of Deloitte's Roadmap *Revenue Recognition* for more information.

Connecting the Dots

In many cases, the fair value of the asset given up is determinable within reasonable limits, the transaction is not an exchange to facilitate sales to customers, and the transaction has commercial substance. Consequently, companies will often use the fair value of the asset given up to determine the gain or loss on sale. Because internally developed assets frequently have no carrying value, a gain on these types of transactions is often realized. However, companies should also consider whether they have any continuing involvement with the asset given up (e.g., retained marketing rights in a certain jurisdiction), which may affect the determination of whether control has been transferred and whether any such gain has been realized.

Note also that certain transactions involving the exchange of inventory between life sciences companies may not meet the exceptions prohibiting the use of fair value and gain or loss recognition. For example, life sciences companies may exchange inventory for use in their respective clinical R&D programs. In these circumstances, life sciences entities should consider the guidance in ASC 845-10-30-15 and 30-16, which state the following:

> **30-15** A nonmonetary exchange whereby an entity transfers finished goods inventory in exchange for the receipt of raw materials or work-in-process inventory within the same line of business is not an exchange transaction to facilitate sales to customers for the entity transferring the finished goods, as described in paragraph 845-10-30-3(b), and, therefore, shall be recognized by that entity at fair value if both of the following conditions are met:
>
> a. Fair value is determinable within reasonable limits.
>
> b. The transaction has commercial substance (see paragraph 845-10-30-4).
>
> **30-16** All other nonmonetary exchanges of inventory **within the same line of business** shall be recognized at the carrying amount of the inventory transferred. That is, a nonmonetary exchange **within the same line of business** involving either of the following shall not be recognized at fair value:
>
> a. The transfer of raw materials or work-in-process inventory in exchange for the receipt of raw materials, work-in-process, or finished goods inventory
>
> b. The transfer of finished goods inventory for the receipt of finished goods inventory. [Emphasis added]

In particular, life sciences entities should consider the classification of inventory (i.e., raw materials, work-in-process, or finished goods) and whether the inventory is "within the same line of business," since these considerations affect the determination of whether to recognize the inventory given up and received at fair value or at cost. In addition, life sciences entities should evaluate whether the assets received will be used as inventory (e.g., can be resold to customers) or for another purpose (e.g., will be used in R&D studies) when determining the applicability of the guidance in ASC 845 and, thus, whether the assets received are recorded at cost or at fair value.

4.2.2.4 Equity Instruments Issued as Consideration

To complete the acquisition of various assets (e.g., patents, licensing arrangements) accounted for as asset acquisitions, a life sciences entity may finance the arrangement by transferring its own equity instruments rather than paying cash or other consideration.

ASC 805-50-30-2 states, in part, that "if the consideration given is not in the form of cash . . . and no other generally accepted accounting principles (GAAP) apply . . . , measurement is based on either the cost which shall be measured based on the fair value of the consideration given or the fair value of the assets (or net assets) acquired, whichever is more clearly evident and, thus, more reliably measurable." As noted above, we are aware of two views in practice regarding the date upon which the acquiring entity should measure the equity instruments it issues in an asset acquisition. The first view is that the guidance in ASC 805-50-25-1 requires the acquiring entity's equity instruments to be measured on the date of the asset acquisition. The second view is that the issuance of shares as consideration in an asset acquisition represents a share-based payment to nonemployees in exchange for goods. Under that view, the acquiring entity would apply ASC 718 when measuring the equity instruments it issued as consideration in an asset acquisition. Applying ASC 718 may result in a measurement date (i.e., the grant date) that precedes the acquisition date for the shares issued.

At its March 3, 2021, agenda prioritization meeting, the FASB decided not to add an agenda item related to the clarification of guidance on certain asset acquisition and nonemployee share-based payment transactions. However, on the basis of the discussion at that meeting, we believe that either view is acceptable provided that entities apply a consistent view.

4.2.2.5 Allocating the Cost

As described in Section C.3 of Deloitte's Roadmap *Business Combinations*, an acquiring entity allocates the cost of an asset acquisition to the assets acquired (and liabilities assumed) on the basis of their relative fair values and is not permitted to recognize goodwill. However, if the fair values of the assets acquired and liabilities assumed are more reliably determinable (e.g., because the consideration is in the form of noncash assets), the entity measures the cost of the transaction by using these fair values. Fair value is measured in accordance with ASC 820.

Goodwill is recognized only if a business is acquired. Thus, no goodwill is recognized in an asset acquisition. Because goodwill represents the expected synergies and other benefits of combining two businesses, one would not expect goodwill to arise in an asset acquisition. If the acquiring entity's cost exceeds the fair value of the net assets acquired, the acquiring entity allocates the difference pro rata on the basis of relative fair values to increase certain of the assets acquired.

Bargain purchase gains are generally not recognized in an asset acquisition. If the fair value of the net assets acquired exceeds the acquiring entity's cost, the acquiring entity allocates the difference pro rata on the basis of relative fair values to reduce certain of the assets acquired. However, such pro rata allocation cannot reduce monetary assets below their fair values. In unusual cases, either pro rata allocation reduces the eligible assets to zero or there are no eligible assets to reduce; we do not believe that an entity should reduce monetary assets below their fair values in such circumstances. However, before recognizing a gain, the entity should consider whether (1) it has appropriately recognized all of the liabilities assumed, any contingent consideration, and any separate transactions or (2) whether the assets received are more reliably measurable than the assets given. If only monetary assets are acquired, the entity should also consider whether the transaction is, in substance, an asset acquisition. For example, if the assets being acquired are primarily cash, the substance of the transaction may be a recapitalization.

4.2.2.5.1 Exceptions to Pro Rata Allocation

As described in Section C.3 of Deloitte's Roadmap *Business Combinations*, pro rata allocation of the acquiring entity's cost to the assets acquired on a relative fair value basis results in the recognition of assets at amounts that are more (or less if a bargain purchase) than their fair values. In deliberating ASC 805-10, ASC 805-20, and ASC 805-30, the FASB discussed a number of exceptions to the recognition and fair value measurement principles in a business combination for assets or liabilities for which the subsequent accounting is prescribed by other GAAP and application of such GAAP would result in the acquirer's recognition of an immediate gain or loss. Examples of such exceptions include assets held for sale, employee benefits, and income taxes. ASC 805-50 provides only general guidance on allocating cost in an asset acquisition. However, we believe that the same principles should apply to an asset acquisition. That is, an acquiring entity should not recognize an asset at an amount that would result in the entity's recognition of an immediate gain or loss as a result of the subsequent application of GAAP if no economic gain or loss has occurred (with the exception of IPR&D assets with no alternative future use, as illustrated in Example 4-5).

Therefore, we believe that certain assets should be recognized at the amounts required by applicable U.S. GAAP or should not be recognized at amounts that exceed their fair values. Such assets (and liabilities) include:

- Cash and other financial assets (other than equity method investments).
- Other current assets.
- Assets subject to fair value impairment testing, such as indefinite-lived intangible assets.
- Assets held for sale.
- Income taxes.
- Employee benefits.
- Indemnification assets.
- Indefinite-lived intangible assets.
- Contract assets measured in accordance with ASC 606 (after adoption of ASU 2021-08).

Example 4-2

Excess of Cost Over the Fair Values of the Assets Acquired

Company A acquires three assets from Company B: machinery and equipment with a fair value of $20,000, a building with a fair value of $50,000, and an indefinite-lived intangible asset with a fair value of $30,000. The total cost of the acquisition, including transaction costs, is $120,000. Company A has determined that the assets do not constitute a business and allocates the cost as follows:

	Fair Value (ASC 820)	Percentage of Fair Value*	Cost of the Acquisition Less Ineligible Asset	Allocated Cost
Machinery and equipment	$ 20,000	29%	$ 90,000	$ 25,714
Building	50,000	71%	90,000	64,286
Indefinite-lived intangible asset	30,000			30,000
	$ 100,000			$ 120,000

* Because the indefinite-lived intangible asset is not recognized at an amount that exceeds its fair value, the percentages are calculated on the basis of only the eligible assets ($20,000 ÷ $70,000 and $50,000 ÷ $70,000).

Sometimes the fair value of the net assets acquired exceeds the acquiring entity's cost (i.e., a bargain purchase), though this is unusual. Allocation of a bargain purchase will reduce assets below their fair values. We believe there are two acceptable views on how to allocate the acquiring entity's cost in such cases. Under the first alternative, which is illustrated in the example below, the same assets that are ineligible for pro rata allocation when cost exceeds the fair value of the assets should also be ineligible for pro rata allocation in a bargain purchase.

Example 4-3

Excess of Fair Values of the Assets Acquired Over Cost (Alternative 1)

Assume the same facts as in Example 4-2 except that the total cost of the acquisition, including transaction costs, is $90,000. Under the first alternative, Company A's cost is allocated as follows:

	Fair Value (ASC 820)	Percentage of Fair Value*	Cost of the Acquisition Less Ineligible Asset	Allocated Cost
Machinery and equipment	$ 20,000	29%	$ 60,000	$ 17,143
Building	50,000	71%	60,000	42,857
Indefinite-lived intangible asset	30,000			30,000
	$ 100,000			$ 90,000

* Because the indefinite-lived intangible asset is recognized at its fair value, the percentages are calculated on the basis of only the eligible assets ($20,000 ÷ $70,000 and $50,000 ÷ $70,000).

Under the second alternative, which is illustrated in the example below, it is appropriate to allocate a bargain purchase to any asset for which the subsequent application of U.S. GAAP would not result in an immediate gain, such as indefinite-lived intangible assets or assets held for sale.

Example 4-4

Excess of Fair Values of the Assets Acquired Over Cost (Alternative 2)

Assume the same facts as in Example 4-2 except that the total cost of the acquisition, including transaction costs, is $90,000. Under the second alternative, Company A's cost is allocated as follows:

	Fair Value (ASC 820)	Percentage of Fair Value*	Cost of the Acquisition Less Ineligible Asset	Allocated Cost
Machinery and equipment	$ 20,000	20%	$ 90,000	$ 18,000
Building	50,000	50%	90,000	45,000
Indefinite-lived intangible asset	30,000	30%	90,000	27,000
	$ 100,000			$ 90,000

* This example assumes that an indefinite-lived intangible asset can be recognized at less than its fair value (but not at greater than its fair value), so the total cost must be allocated to all of the acquired assets.

4.2.2.5.2 Contingencies

An entity accounts for gain or loss contingencies acquired or assumed in an asset acquisition in accordance with ASC 450. A loss contingency is recognized when it is probable that a loss has been incurred and the loss can be reasonably estimated. A gain contingency is not recognized until the gain is realized and therefore is not recognizable in an asset acquisition. If an acquiring entity acquires a gain or loss contingency in an asset acquisition, but the contingency does not qualify for recognition on the date of acquisition, the entity will allocate the cost of the acquisition only to the recognizable assets acquired and may initially recognize certain assets at more or less than their fair values because of the nonrecognition of the contingency.

4.2.2.5.3 Intangible Assets

An entity recognizes intangible assets that are acquired in an asset acquisition if they meet the asset recognition criteria in FASB Concepts Statement 5, even if they are not separable or do not arise from contractual rights. There is a lower threshold for recognizing intangible assets in an asset acquisition than in a business combination (with the exception of IPR&D, which is discussed in Section 4.2.2.5.4). In a business combination, if the consideration transferred includes amounts for intangible assets that do not qualify for recognition (e.g., an assembled workforce), those unrecognized intangible assets are subsumed into goodwill while the assets acquired are still generally recognized at their fair values. However, in an asset acquisition, no goodwill is recognized. If the consideration paid includes amounts for intangible assets that were not separately recognized, the cost of the acquisition would be allocated to the recognizable assets and those assets may be recognized at amounts that exceed their fair values. Since there is no residual into which unrecognized intangible assets could be subsumed, the FASB decided that the threshold for recognizing intangible assets in an asset acquisition should be lower than in a business combination.

Entities recognize finite-lived intangible assets acquired in an asset acquisition on the basis of relative fair values. However, because indefinite-lived intangible assets are subject to fair value impairment testing after the acquisition date, we believe that they should not be recognized at an amount that exceeds fair value, as discussed in Section 4.2.2.5.1.

4.2.2.5.4 IPR&D Assets

An acquiring entity must allocate, on the basis of relative fair values, the cost of the acquisition to both the tangible and intangible R&D assets acquired. On the date of acquisition, the acquiring entity expenses IPR&D assets with no alternative future use and capitalizes those with an alternative future use in accordance with ASC 730.

One of the most significant differences between the accounting for an asset acquisition and that for a business combination lies in the accounting for IPR&D assets. In a business combination, the acquirer must recognize all IPR&D assets at fair value and initially characterize them as indefinite-lived intangible assets, regardless of whether the IPR&D assets have an alternative future use. In EITF Issue 09-2, the Task Force considered amending ASC 730 with respect to IPR&D assets acquired in an asset acquisition; however, the Task Force was unable to reach a consensus and removed the project from its agenda. Therefore, entities continue to apply the guidance in ASC 730 in accounting for IPR&D assets acquired in an asset acquisition.

Connecting the Dots

A life sciences entity may acquire an equity interest in an entity that is engaged in R&D activities. When the equity method of accounting is applied to the investment, the entity should evaluate whether the investee meets the definition of a business. If the investee meets the definition of a business, the entity allocates cost to IPR&D under the acquisition method principles of ASC 805-20 and accounts for the basis difference as if the investee were a consolidated subsidiary. If the investee does not meet the definition of a business, the entity allocates cost to IPR&D under the asset acquisition principles of ASC 805-50 but immediately expenses that amount if the IPR&D has no alternative future use.

The example below illustrates how to allocate the cost of an asset acquisition of IPR&D when fair value exceeds cost.

Example 4-5

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

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

Company A accounts 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, A concludes 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.

In the example above, 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 could 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). Accordingly, the entity could 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.

If this guidance were applied, 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 is greater than the up-front consideration transferred. However, Company A has concluded that applying such guidance by analogy would not be appropriate 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 this guidance would result in an unintended outcome. Specifically, it would cause the future milestone payment to be expensed as IPR&D as of the acquisition date. In contrast, if this guidance were not applied, the future milestone payment would potentially be recorded on a later date (i.e., when it is otherwise probable that the milestone will be achieved and will most likely be capitalized, since the milestone payment is triggered only upon regulatory approval). 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.

4.2.2.6 Transactions That Are Separate From an Asset Acquisition

An acquiring entity and the seller of the assets may have a preexisting relationship or other arrangement before negotiations for the acquisition begin, or they may enter into an arrangement during the negotiations that is separate from the acquisition of the assets (e.g., a life sciences entity may enter into contemporaneous supply arrangements for a product during a specified period while the acquiring entity completes certain regulatory requirements to manufacture and commercialize the product). ASC 805-50 includes only general principles related to accounting for an asset acquisition. While the guidance does not explicitly state so, we believe that those principles presume that the cost of the acquisition includes only amounts related to the acquisition of the asset or group of assets and not amounts related to separate transactions. Further, we believe that in the absence of specific guidance, an entity should analogize to ASC 805-10-25-20 and ASC 805-10-25-22, which provide guidance on identifying and accounting for transactions that are separate from a business combination. Under this guidance, the acquirer must, when applying the acquisition method, recognize "only the consideration transferred for the acquiree and the assets acquired and liabilities assumed in the exchange for the acquiree." Any separate transactions must be accounted for separately from the business combination in accordance with the relevant GAAP.

Example 4-6

Asset Acquisition and Related Supply Agreement

Company A enters into an agreement with Company B to acquire machinery and equipment that will be used to manufacture Product X. The machinery and equipment do not meet the definition of a business in ASC 805-10. In addition to stipulating a cash amount to be paid by A upon transfer of the machinery and equipment, the agreement specifies that A will provide B with a specified number of units of Product X for two years after the acquisition at a fixed per-unit price that is determined to be below market.

In determining the cost of the asset acquisition, A should take into account both the amount it paid upon transfer of the machinery and equipment and the value transferred to B under the below-market fixed-price supply agreement. Company A would recognize a balance sheet credit on the date of acquisition for the unfavorable supply contract; the credit would be recognized in income as units of Product X are delivered.

Example 4-7

Asset Acquisition That Settles a Dispute

Company A has an agreement with Company B that gives B the exclusive right to distribute A's goods in a specific region. Company B asserts that A has inappropriately given the distribution right to B's competitor. Company A and B decide to settle the dispute so that A reacquires the distribution right from B. The distribution right does not meet the definition of a business in ASC 805-10. Company A believes that if it does not reacquire the distribution right, it is liable to B for breach of contract.

In determining the cost of the asset acquisition, A should exclude from this cost any amount related to the dispute's settlement to avoid the capitalization of what would otherwise be an operating expense if paid separately from the asset acquisition.

See Section 6.2.1.2 for further discussion related to identifying elements in a litigation settlement, including SEC staff views expressed in a speech delivered at the 2007 AICPA Conference on Current SEC and PCAOB Developments.

4.2.3 Business Combinations

See Deloitte's Roadmap *Business Combinations* for insights into and interpretations of the guidance in ASC 805 on business combinations, including, among other acquisition method guidance, that on measurement of (1) assets acquired and liabilities assumed and (2) goodwill and consideration transferred. Some of the more common issues that life sciences entities have faced when accounting for business combination transactions are discussed below.

4.2.3.1 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. Specifically, under ASC 805 and ASC 350, an acquirer recognizes all tangible and intangible R&D assets acquired in a business combination (IPR&D) at fair value as of the acquisition date and subsequently accounts for them as indefinite-lived intangible assets until completion or abandonment of the associated R&D efforts. An acquirer recognizes and measures such assets independently of (1) whether the acquiree had previously capitalized any amounts related to its R&D activities or (2) the amounts previously expended by the acquiree in connection with those activities.

In addition, an acquirer recognizes tangible and intangible assets that result from, or are to be used in, R&D activities as assets regardless of whether the acquired assets have an alternative future use. Acquired IPR&D assets must be measured at their acquisition-date fair values. Uncertainty about the outcome of an individual project does not affect the recognition of IPR&D but does affect its fair value measurement.

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. (Refer to Chapter 3 for additional discussion of the types of costs that meet the definition of R&D.) R&D activities are considered to be within the scope of ASC 730 only 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.

Example 4-8

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 incurred significant costs related to the R&D of a drug compound, all of which it expensed as incurred under ASC 730. Company A plans to continue these R&D efforts in hopes of obtaining regulatory approval for the drug compound and launching it 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).

4.2.3.2 Identifying IPR&D

The AICPA Accounting and Valuation Guide *Assets Acquired to Be Used in Research and Development Activities* (the "AICPA Guide") includes guidance on identifying IPR&D. The AICPA Guide observes that "incompleteness" is an essential characteristic of IPR&D. Paragraphs 2.54 and 2.55 of the AICPA Guide state the following:

> **2.54** 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.
>
> **2.55** 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.

Example 4-9

Company T is the owner of patented IP related to a developed product that it currently markets and sells to customers. Company T also uses the IP in certain ongoing R&D activities.

Company A acquires T in a business combination. Company A expects to continue using the IP in the sale of the currently commercialized product as well as in ongoing and identified future R&D activities.

In accounting for the acquisition of the patented IP, A would not assign the acquired IP an indefinite life upon acquisition because the IP (1) is not being used solely for the purpose of an ongoing R&D activity, (2) is already a completed asset that is being used as intended (i.e., it does not exhibit the characteristics of "incompleteness" as defined in the AICPA Guide), and (3) may reasonably be expected to produce economic benefits for a finite period. The fact that the patent is also being used in certain ongoing R&D activities and will be used in identified future R&D activities does not necessarily mean that the patent itself should be assigned an indefinite life. In this fact pattern, the acquired patent would be accounted for as a finite-lived intangible asset in accordance with ASC 350-30-25 and amortized over its assigned life.

However, paragraph 2.37 of the AICPA Guide clarifies that "to the extent that individually completed intangible assets are solely and directly related to IPR&D projects that are still in development (for example, in the pharmaceutical industry, a patent on a compound that has not yet been approved), such assets may be aggregated with other intangible assets used in R&D activities. That is, an acquirer would recognize one asset for each IPR&D project, which would comprise all the intangible assets used exclusively in that project, and that asset would be assigned an indefinite useful life."

Further, paragraph 2.56 of the AICPA Guide 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 expects[fn 9] 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.
>
> [fn 9] 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*.

In evaluating these factors, entities have raised questions about whether a product can be considered incomplete if all activities have been completed other than obtaining regulatory approval.

Example 4-10

Company X enters into an agreement to acquire Company Y that will be accounted for as a business combination. The agreement includes the acquisition of rights to a generic version of a branded product. The product's ANDA has been submitted to the FDA for approval, which is expected in the current fiscal period. Company X does not anticipate incurring any additional expense to bring the product to commercialization.

The AICPA Guide provides the following Q&A in paragraph 2.62:

> *Question 3:* Company A acquired Company T in a business combination. At the acquisition date, Company T had an application to market a new drug pending FDA approval. Both Company A and T believe that Company T had completed all necessary tasks related to the filing (including having obtained satisfactory test results), and they believe that they will ultimately obtain FDA approval. Is the project **incomplete**?
>
> *Answer:* Yes. Industry experience shows that there are uncertainties about obtaining approval for a new drug upon filing with the FDA. FASB ASC 730-10 does not specifically address whether costs of obtaining FDA approval are R&D; however, the task force believes that such future expenditures satisfy the condition that, to be considered incomplete, additional R&D costs must be expected to be incurred by the reporting entity. [Emphasis added]

Therefore, in the fact pattern involving X and Y, X would classify the related product rights as an IPR&D asset until final approval is received from the regulator, at which point the IPR&D asset would become a finite-lived asset (i.e., an asset that resulted from R&D activities).

Connecting the Dots

Through business development activities, companies acquire assets in various stages of product life cycles. These assets may include products under "discontinued" status with the FDA at the time of acquisition that the acquirer subsequently intends to commercialize. As defined by the FDA, discontinued drug products represent "approved products that have never been marketed, have been discontinued from marketing, are for military use, are for export only, or have had their approvals withdrawn for reasons other than safety or efficacy after being discontinued from marketing."

In determining the accounting for purchased assets under "discontinued" FDA status (i.e., IPR&D vs. product rights), acquirers should consider the extent of activities required to commercialize those products as included in ASC 730-10-55-1 (activities typically included in R&D) and ASC 730-10-55-2 (activities typically excluded from R&D).

For example, when an acquired discontinued product has been "kept up-to-date" to meet regulatory requirements (e.g., labeling, packaging), it may be a relatively straightforward administrative effort to bring the product back to market. In this case, preparers might consider it appropriate to capitalize the acquired product rights on the balance sheet (with the intent to classify the product as a finite-lived intangible asset) and defer amortization expense until the product is commercialized. In accordance with ASC 350, amortization of definite-lived intangible assets should be recorded on the basis of the pattern in which the economic benefits are consumed or otherwise used — or, in this case, when the product is sold to a customer (in a manner similar to how an entity would account for construction-in-process assets, the depreciation of which is not recorded until the assets are placed into service).

4.2.3.3 Defensive IPR&D Acquired in a Business Combination

In completing a business combination, a life sciences entity may acquire an IPR&D asset even though it does not intend to pursue the R&D project to completion. Instead, the entity may have strategic intentions to hold or "lock up" the IPR&D asset to prevent competitors from obtaining access to the asset and thereby "defend" the value of other IPR&D assets or developed products in the entity's portfolio.

Chapter 2 of the AICPA Guide addresses relevant considerations related to defensive assets. It notes that while ASC 350-30-35-5A and 35-5B generally govern the accounting treatment for defensive intangible assets, IPR&D is specifically excluded from the scope of that guidance. Accordingly, paragraph 2.31 of the AICPA Guide discusses defensive IPR&D as follows:

> [I]f the reporting entity intends to hold (or lock up) an acquired intangible asset to prevent others from obtaining access to the asset in order to "defend" the value of other intangible assets used in R&D activities, the task force believes that such asset would be considered "used in R&D activities." Therefore, in accordance with guidance in FASB ASC 350-30-35-17A, the task force recommends that such assets be assigned an indefinite life until the "defended" IPR&D project is completed or abandoned.

At the time of acquisition, the acquiring entity would assign the IPR&D asset's fair value as of the measurement date based on the perspective of a market participant.

The AICPA Guide highlights that there may be situations in which individually *completed* intangible assets are used in R&D activities. In general, the task force believes that "incompleteness" (as defined in paragraph 2.17 of the AICPA Guide) is an essential characteristic of IPR&D assets. Therefore, the task force believes that when intangible assets used in R&D activities lack that characteristic (i.e., the assets are complete) but are being used in the way they were intended, the intangible assets should not be considered IPR&D assets and should be accounted for in accordance with their nature (and not assigned an indefinite useful life). However, in a manner specific to the pharmaceutical industry, paragraph 2.37 of the AICPA Guide provides the following clarification that preparers may consider in the context of identifying and accounting for the assets:

> [T]o the extent that individually completed intangible assets are solely and directly related to IPR&D projects that are still in development (for example, in the pharmaceutical industry, a patent on a compound that has not yet been approved), such assets may be aggregated with other intangible assets used in R&D activities. That is, an acquirer would recognize one asset for each IPR&D project, which would comprise all the intangible assets used exclusively in that project, and that asset would be assigned an indefinite useful life.

For further insight into the accounting for defensive IPR&D assets, consider the example below, which is adapted from paragraph 2.33 of the AICPA Guide.

Example 4-11

Company A acquires Company B. At the time of the acquisition, B owns patented technology and know-how that are in development and, if successfully completed, would compete with an existing pharmaceutical technology under development by A. Company A does not intend to pursue further development of the patented technology and know-how of B. Rather, A will hold B's patented technology and know-how to "protect" the value of the technology under development by A.

To record and subsequently measure the patented technology and know-how of B, A would perform "day 1" and "day 2" activities as follows:

- *Day 1* — Company A would assign to the IPR&D assets acquired from B a fair value (in a manner consistent with how a market participant would do so), as well as an indefinite life.
- *Day 2* — Company A would begin amortizing the acquired assets upon completing the development of its technology. However, if the development efforts were abandoned, A would expense the carrying amount of the acquired technology in the period of abandonment (unless A intended to develop the acquired technology in the event that the development of its existing technology were unsuccessful). Note that although A acquired and held the patented technology and know-how for defensive purposes, A would need to continue evaluating the acquired assets for impairment during the period in which it was developing its own patented technology and know-how.

Connecting the Dots

In assessing the accounting impact of an acquired IPR&D asset, preparers should collaborate cross-functionally within their organization to fully understand the strategic objectives related to the project as well as in context within the existing asset portfolio. The AICPA Guide cautions preparers that when an entity assesses the complement of acquired IPR&D, it may take time for the acquirer to determine what it might ultimately do with certain assets (in evaluating defensive relevance) to inform the appropriate accounting. The task force notes that before concluding that certain acquired IPR&D (that does not constitute the primary asset in a transaction) has no further use, the acquirer would need to determine that continued ownership of the asset will not contribute to an increase in (or maintenance of) the value of other assets that the acquirer owns.

4.2.3.4 Outlicensing Arrangements

Life sciences companies may acquire intangible assets that have been, or will be, outlicensed to others. The AICPA Guide specifically addresses outlicensing arrangements. Paragraph 2.10 states, in part:

> 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 connection with a business combination. In contrast, a contract-based intangible would typically be accounted for as a finite-lived intangible asset (i.e., it would be subject to amortization).

For example, assume that the IP 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 IP 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.

Connecting the Dots

To reach such accounting conclusions, the licensor must carefully analyze the nature and extent of its ongoing involvement with the R&D project. In certain outlicensing arrangements, the licensor retains some level of continuing involvement with the IP. 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).

4.2.3.5 Determining the Unit of Account for IPR&D

Under ASC 805, an acquiring entity recognizes acquired IPR&D in a business combination at fair value as of the acquisition date. However, because ASC 805 does not provide any specific guidance on identifying the unit of account for identifiable assets, the acquiring entity must use judgment to determine whether separately identifiable IPR&D assets that share similar characteristics may be aggregated into a single unit of account.

The determination of a unit of account will depend on the relevant facts and circumstances of each acquisition. When making that determination, an entity may consider the following factors in paragraph 2.20 of the AICPA Guide:

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

The example below illustrates the application of these factors.

Example 4-12

On September 30, 20X8, Company X acquires Company Y in a transaction accounted for as a business combination. Company Y has been pursuing a new therapy designed to help patients suffering from Crohn's disease. In the European Union, all clinical trials have been completed and the appropriate applications have been filed, but the product is awaiting regulatory approval. In the United States, the same product is under development and not as far advanced; the product has only just commenced phase III clinical trials. In addition, if the product is approved in both the European Union and the United States, patent protection is expected to expire significantly later in the United States.

Given the above factors, X determines that two IPR&D assets should be recognized: one for the European Union and another for the United States. In reaching this determination, X considered that the IPR&D project is in different stages of development in the jurisdictions, remaining costs are expected to be significantly higher in the United States as a result of the additional studies that remain to be completed, and the useful life of the asset is expected to be greater in the United States as a result of the patent protection period.

Refer to the AICPA Guide for additional examples.

The example below, which is adapted from paragraph 2.21 of the AICPA Guide, further illustrates the application of these factors.

Example 4-13

Company A acquired Company T in a business combination. As of the acquisition date, T was pursuing completion of an IPR&D project that, if successful, would result in a drug for which A would seek regulatory approval in the United States, Europe, and Japan.

Regarding the unit of account for the acquired incomplete IPR&D project, A's determination of whether to recognize one IPR&D asset (representing the compound) or three IPR&D assets (representing the compound in each of the jurisdictions in which it is expected to be sold in) requires considerable judgment because it is likely that the IPR&D project is "separable" as either a "global" or a "jurisdictional" asset.

To determine the appropriate unit of account for the acquired incomplete IPR&D project, A may consider the factors in the table below.

Example 4-13 (continued)

Factors Indicating That Recording a Single (Global) IPR&D Asset May Be Appropriate	Factors Indicating That Recording Three Separate Jurisdictional IPR&D Assets May Be Appropriate[4]
• The IPR&D project is still in the early development phase, at which point it may be less likely to have separate units of account for different jurisdictions than in later phases of development.	• The IPR&D project is in a later phase of development (e.g., the product phase for the pharmaceutical industry), and development risks associated with different jurisdictions are known.
• The nature of the activities and costs necessary to further develop the IPR&D project are substantially the same (e.g., the development of the project will occur centrally, and A intends to incur only a small portion of the total development costs to obtain approval within each regulatory jurisdiction toward the later stages of testing).	• The nature of the activities and costs necessary to further develop the IPR&D project are not substantially the same. For example, the development of the project will occur centrally for a portion of the process; however, the extent of separate regulatory approval costs is expected to be a significant portion of the overall development cost.
• On the basis of historical experience or expectations, the risks associated with the further development of the IPR&D project are substantially the same (e.g., A believes that it will most likely obtain approval in all three jurisdictions or in none of the jurisdictions, although the timing of approval may differ).	• The risks associated with the further development of the IPR&D project are not substantially the same. For example, A believes that the risk of obtaining approval in each jurisdiction is different, and it does not believe that approval in one jurisdiction is relevant to approval in other jurisdictions.
• The amount and timing of benefits expected to be derived in the future from the developed asset(s) and the expected economic life of the developed asset(s) are substantially the same (e.g., if the patent applications are approved, the patent is expected to have approximately the same life in all three jurisdictions).	• The amount and timing of benefits expected to be derived in the future from the developed asset(s) and the expected economic life of the developed asset(s) are not substantially the same. For example, if the patent applications are approved, the patent life is expected to be different for each of the three jurisdictions.
• Company A intends to manage strategy, manufacturing, advertising, and selling costs from the perspective of the global brand, not the individual jurisdictions where the product will be sold.	• Company A intends to manage strategy, manufacturing, advertising, and selling costs separately in each jurisdiction in which the compound is sold.
• On the basis of historical experience and current intentions, A believes that once completed, the compound (if ever transferred) would be transferred in one worldwide arrangement.	• On the basis of historical experience and current intentions, A believes that once completed, the compound (if ever transferred) would not be transferred as a single asset.

[4] Footnote 5 in paragraph 2.21 of the AICPA Guide points out that "[a]lthough . . . the unit of account determination [illustrated] is based on different geographic locations, the same logic can be applied to different drug indications (for example, physical ailment, disease state, treatment regime)."

Other questions about determining the unit of account frequently arise when IPR&D assets acquired in a business combination are associated with a preexisting contingent consideration arrangement. Examples of business combinations involving such IPR&D assets are addressed in the Q&As below, which are reproduced from paragraphs 2.14 and 2.15 of the AICPA Guide.

> **2.14** *Question 1:* Company A acquired Company T in a business combination. Prior to the date of the acquisition, Company T had entered into a licensing arrangement with Company L. Pursuant to the terms of the license, Company T acquired rights related to a drug candidate that had been patented by Company L. At the time of Company T's license, the drug candidate had not yet been approved for marketing. Under the terms of the license, Company T acquired all of the rights to develop, manufacture, and sell the drug candidate. In exchange for these rights, Company T made a payment at the inception of the agreement and is obligated to make additional payments if certain substantive milestones are achieved (for example, initiation of phase III clinical trials), as well as royalties based on a percentage of sales of the drug if it is approved for marketing. Should the milestone and royalty payments be considered elements of the acquired contract-based intangible or a separate unit of account?
>
> *Answer:* Provided that separation is not required by accounting literature, the milestone and royalty obligations may be considered elements of the acquired contract-based intangible, rather than a separate unit of account. In determining the fair value of this contract-based intangible asset, Company A will most likely use an income approach, such as a discounted cash flow method, that will consider all the anticipated cash flows associated with this contract that a market participant would consider. Accordingly, in addition to the anticipated development costs, revenues, cost of product, commercialization costs, and other cash flows, Company A would also consider the anticipated milestones and royalties and, if necessary, would adjust the cash flows to reflect market participant assumptions. The milestone and royalty obligations would, therefore, reduce the fair value of the licensed IPR&D asset.
>
> **2.15** *Question 2:* Company T acquired Company L in a business combination. At the acquisition date, Company L was developing a patented drug candidate, which Company T recorded as an IPR&D asset. The terms of the acquisition agreement required Company T to make a cash payment at the acquisition date, as well as additional cash payments to the former shareholders of Company L if certain substantive milestones were achieved in the future relating to the acquired drug candidate (for example, initiation of phase III clinical trials). Company T accounted for the contingent milestone payments as contingent consideration and, therefore, recorded a contingent consideration liability at fair value at the acquisition date. Company A subsequently acquired Company T in a business combination. At the time of the acquisition, none of the milestones had been achieved. Company A recorded the IPR&D asset relating to the patented drug candidate that was previously recorded by Company T at fair value at the acquisition date. When determining the fair value of the IPR&D asset, should Company A consider the preexisting contingent consideration arrangement as an element of the IPR&D asset or as a separate unit of account?
>
> *Answer:* Because FASB ASC 805 requires contingent consideration arrangements of an acquiree that have been assumed by the acquirer in a business combination to be separately recognized, Company A should treat the preexisting contingent consideration arrangement as a separate unit of account. Thus, when determining the fair value of the IPR&D asset, Company A should not include the future milestone payments in the discounted cash flow analysis to avoid double-counting.

4.2.3.6 Subsequent Accounting for Acquired IPR&D Assets

Under ASC 805, the acquiring entity recognizes IPR&D assets at fair value as of the acquisition date. After those acquired IPR&D assets are recognized in a business combination, the acquiring entity should apply the guidance in ASC 350. 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 paragraphs 350-30-35-18 through 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 paragraph 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.

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.

Example 4-14

On June 30, 20X8, 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, 20Y1, 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, 20X8, to June 30, 20Y1, 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 A's 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, 20Y1 (the date of abandonment), in the income statement.

Example 4-15

Assume the same facts as in the example above except that A successfully completes its IPR&D project on July 1, 20Y1, 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 asset as of July 1, 20Y1 (the date the IPR&D project is successfully completed), and amortize the asset over the related product's useful life. That is, the acquired IPR&D asset's 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, 20Y1.

4.2.3.7 IPR&D Impairment Considerations

After a business combination, events or conditions may arise that result in a decrease in the value of indefinite-lived IPR&D assets, potentially leading to impairment. Under U.S. GAAP, guidance is provided on when to test for impairment, how to determine whether impairment should be recognized, and how to measure and record such impairment in the financial statements.

ASC 350-30-35-17 through 35-18A note the following about impairment testing of IPR&D assets:

ASC 350-30

35-17 If an intangible asset that is not being amortized is subsequently determined to have a finite useful life, the asset shall be tested for impairment in accordance with paragraphs 350-30-35-18 through 35-19. That intangible asset shall then be amortized prospectively over its estimated remaining useful life and accounted for in the same manner as other intangible assets that are subject to amortization.

35-17A Intangible assets acquired in a business combination or an acquisition by a not-for-profit entity that are used in research and development activities (regardless of whether they have an alternative future use) shall be considered indefinite lived until the completion or abandonment of the associated research and development efforts. During the period that those assets are considered indefinite lived, they shall not be amortized but shall be tested for impairment in accordance with paragraphs 350-30-35-18 through 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 this Section. Consistent with the guidance in paragraph 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.

35-18 An intangible asset that is not subject to amortization shall be tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired.

35-18A An entity may first perform a qualitative assessment, as described in this paragraph and paragraphs 350-30-35-18B through 35-18F, to determine whether it is necessary to perform the quantitative impairment test as described in paragraph 350-30-35-19. An entity has an unconditional option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test as described in paragraph 350-30-35-19. An entity may resume performing the qualitative assessment in any subsequent period. If an entity elects to perform a qualitative assessment, it first shall assess qualitative factors to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that an indefinite-lived intangible asset is impaired.

Life sciences entities may encounter various challenges in performing an impairment assessment of IPR&D assets. Entities should consider the following questions when performing a qualitative assessment:

- *Regulatory considerations* — Has the product received approval in any markets since the previous analysis? Are there changes to the regulatory environment or matters that suggest any loss of value for the asset (e.g., FDA or other regulatory communication suggesting delay)? Have there been any negative results since the previous analysis either internally or through public sources (clinicaltrials.gov)? What is the status of clinical testing, and is the estimated launch date still achievable? Is there any delay in the next expected regulatory milestone or indication according to plan?
- *Commercial and legal considerations* — Are there any major changes in the competitive landscape for the IPR&D product (e.g., competitive product launched or filed/delayed, price decrease of existing product)? Is the projected market share still realistic? Have there been any changes to the patents or other exclusive rights? Are there changes to the commercial or legal environment that may suggest any loss of value for the asset?

- *Financial and strategic considerations* — Are there future strategic plans to continue/discontinue clinical testing? Is there any change in the amount and timing of the expected future R&D costs? Are any competing products in development expected to affect product launch determinations or subsequent market opportunity? Is there any previous analysis? Are there any changes in the amount and timing of the projected operating costs or projected revenues? Is there any change in the estimated PTRS? Is there sufficient funding available to complete the development of the product and to launch the product? Are there any other financial or strategic reasons that may suggest loss of use or another decline in value?

For further description of the qualitative assessment and relevant impairment considerations, see ASC 350-30-35-18A through 35-18F. Also, refer to the AICPA Guide for additional considerations related to performing a quantitative impairment analysis.

4.2.3.8 Settlement of Preexisting Relationships

In a business combination, the acquirer and acquiree may have a preexisting relationship, such as a collaborative agreement to jointly develop or promote a particular compound.

If a business combination effectively results in the settlement of a preexisting relationship between an acquirer and an acquiree, the acquirer would recognize a gain or loss. ASC 805-10-55-21 indicates how such a gain or loss should be measured.

ASC 805-10

55-21 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.

Note that if a preexisting contract is otherwise cancelable without penalty, no settlement gain or loss would be recognized. The acquirer's recognition of an asset or liability related to the relationship before the business combination will affect the calculation of the settlement.

When a business combination results in the settlement of a noncontractual relationship, such as a lawsuit or threatened litigation, the gain or loss should be recognized and measured at fair value. This settlement gain or loss may differ from any amount previously recorded under the contingency guidance in ASC 450.

Connecting the Dots

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.

See Section 6.2.2 of Deloitte's Roadmap *Business Combinations* for additional information on settlement of preexisting relationships.

4.2.3.9 Initial and Subsequent Accounting for Contingent Consideration

The acquirer must distinguish between contingent consideration (see ASC 805-10-20) and preexisting contingencies assumed in the acquisition (see the definition of a contingency in ASC 450-10-20). In accordance with ASC 805-30-25, contingent consideration is recorded at fair value as part of the total consideration transferred by the acquirer in a business combination. The fair value of contingent consideration is considered to be part of the purchase price and is recorded on the balance sheet either as a liability or within equity (or, less commonly, as an asset). Key inputs may include estimated timing and the probability that the conditions or milestones in the arrangement will be met. Acquirers also need to apply judgment when assessing the probability that each potential outcome will be achieved.

Connecting the Dots

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.

After the acquisition date, if the acquirer classifies a contingent consideration arrangement as an asset or a liability, the asset or liability is remeasured to fair value each reporting period until the contingency is resolved. The acquirer recognizes changes in fair value in earnings each period unless the acquirer designates the arrangement as a cash flow hedging instrument to which the provisions of ASC 815-10 apply.

However, if the contingent consideration is classified as an equity instrument, it is not remeasured. The initial amount recognized for contingent consideration classified as equity is not adjusted, even if the fair value of the arrangement changes. The subsequent settlement of the arrangement on the date the contingency is resolved is accounted for within equity.

Adjustments made during the measurement period that pertain to facts and circumstances that existed as of the acquisition date are recognized as adjustments to goodwill. The acquirer must consider all pertinent factors in determining whether information obtained after the acquisition date should result in an adjustment to the provisional amounts recognized or whether that information results from events that occurred after the acquisition date. For example, earnings targets that are met, changes in share prices, and FDA approvals are all changes that occur after the acquisition date. Changes in fair value resulting from these items are recognized in earnings and not as adjustments to goodwill.

When a contingency related to contingent consideration is not met (e.g., earnings targets specified in an arrangement are not achieved), the acquirer should consider whether this factor represents an indicator that goodwill associated with the business combination should be tested for impairment.

Example 4-16

Company A acquires Company B for $15 million in a transaction accounted for as a business combination. The parties further agree that if the FDA approves B's lead compound, A will pay the former owners of B an additional $6 million as well as a royalty equal to 2 percent of future net sales in the United States. The contingent consideration arrangement is classified as a liability and has an acquisition-date fair value of $14 million.

At the end of each reporting period after the acquisition date, the arrangement is remeasured to its fair value, with changes in fair value recorded in earnings. For example, if the likelihood of achieving FDA approval increases, the fair value of the contingent consideration would most likely increase, resulting in an additional charge in the income statement. Conversely, if the contingency is not met or its fair value declines, any accrued liability would be reversed into income.

Connecting the Dots

After the balance sheet date but before financial statements are issued or are available to be issued, events may occur that affect the value of contingent consideration recognized as a liability on the balance sheet as part of a business combination. For example, contingent consideration may exist in the form of a regulatory approval–based milestone payment due to the seller, and such approval may occur, or notification of regulatory denial may be received, after the balance sheet date. Questions often arise about whether this type of event should be treated as a recognized or nonrecognized subsequent event. ASC 855-10-55-2(f) notes that changes in the fair value of assets or liabilities (financial or nonfinancial) after the balance sheet date but before financial statements are issued or are available to be issued represent nonrecognized subsequent events. Because contingent consideration liabilities are recognized at fair value, any change in fair value after the balance sheet date but before financial statements are issued or are available to be issued would be treated as a nonrecognized subsequent event. In such circumstances, preparers should evaluate the significance of the change in fair value of the contingent consideration and consider whether it may be of such a nature that it must be disclosed to keep the financial statements from being misleading. For such matters, ASC 855-10-50-2 notes that companies should disclose the nature of the event as well as an estimate of its financial effect (or a statement that such an estimate cannot be made).

See Section 5.7 of Deloitte's Roadmap *Business Combinations* for additional information on recognition and measurement of contingent consideration in a business combination.

4.2.4 SEC Comment Letter Themes Related to Business Combinations and Asset Acquisitions

Below are examples of certain SEC staff comments that registrants in the life sciences industry and other industries have received regarding their accounting for business combinations and asset acquisitions.

For more information about SEC comment letter themes that pertain to the life sciences industry, see Deloitte's Roadmap *SEC Comment Letter Considerations, Including Industry Insights*.

4.2.4.1 Business Combination Versus Asset Acquisition Accounting Determination

Examples of SEC Comments

- You recorded the . . . acquisitions as asset acquisitions. Please tell us, for each acquisition, why you believe the acquisitions are not required to be recorded as an acquisition of a business pursuant to ASU 2017-01 [as codified in ASC 805]. In this regard, please specifically address the following:
  - As it appears you acquired both tangible and intangible assets in the [first acquisition] and the [subsequent] acquisition appears to relate to assets with significantly different risks, please confirm our understanding that the acquisitions did not meet the "practical screen" in ASC 805-10-55-5A through 55-5C as the term is used in ASC 805-10-55-5. Refer also to the example in ASC 805-10-55-68.
  - Please address each of the criteria in ASC 805-10-55-5E in determining whether or not a substantive process was acquired, that together with the input acquired, significantly contribute to the ability to create outputs.
- With respect to the [p]roduct [r]ights [a]cquired from [Company A], your response does not consider risks, other than marketing and promotional risks. At a minimum, please address the following potential risks:
  - The drugs are intended to treat significantly different conditions which bear the risk of potentially different long-term side effects. Branded drugs are subject to litigation which may not occur for years after being marketed;
  - Each drug has a significantly different potential customer base with different regulatory risks;
  - Each drug has different risks with respect to being on drug formulary lists; and
  - Although the products have been marketed for more than [X] years, the competition differs for each of the different drugs, despite the lack of promotional activity for the drugs.

  In light of the risks, other than marketing and promotional risk, please tell us why you believe the product rights acquired from [A] do not have significantly different risk characteristics and thus meet the "practical screen" test in ASC 805-10-55-5A through 55-5C. If the acquisitions do not meet the "practical screen test" please address each of the criteria in ASC 805-10-55-5E in determining whether or not a substantive process was acquired, that together with the input acquired, significantly contribute to the ability to create outputs.
- We note that . . . you acquired IPR&D and hired staff to expand . . . and this resulted in $[X] million of IPR&D and $[X] million of goodwill. As this appears to be an asset acquisition rather than a business combination, please clarify for us how this represents a business combination under ASC 805. Specifically refer to ASC 805-10-55-3A through 9.

Accounting for a transaction as a business combination differs significantly from accounting for a transaction as an asset acquisition, as discussed in Section 4.2.2. Consequently, when acquisitions occur, it is important to determine whether what is being acquired meets the definition of a business under ASC 805. Given the SEC staff's historical focus on how life sciences companies have applied the definition of a business, registrants in the life sciences industry should be mindful that the SEC staff may ask questions about (1) whether an acquired set meets the definition of a business and (2) the basis for the registrant's conclusions.

4.2.4.2 Recognition of Assets and Liabilities

Examples of SEC Comments

- You disclose . . . that you acquired the legal rights, permits, licenses and assets of [various entities]. However, it appears the purchase prices were allocated entirely to licenses. Please tell us why the purchase prices were not allocated to other assets and/or liabilities acquired.
- We note your acquisition of [Entity B] and Subsidiaries and your disclosure that it will expand your [product offering] in North America and allow you to diversify your business, leverage your distribution network and infrastructure and increase your market reach. Additionally, you stated the transaction is expected to provide synergies, enhancing your ability to better serve your combined customers' needs . . . . Given the magnitude of the amount of goodwill recognized, please explain further the specific synergies you identified, relative magnitude of each, and consideration for including such discussion in your disclosures. Also, please explain to us in performing the purchase price allocation, how you evaluated the purchase for the existence of any other intangible assets.

Registrants need to consider the provisions of ASC 805 in making the appropriate accounting determination of whether a transaction represents a business combination or an asset acquisition. Upon completing this assessment, registrants need to assign amounts to assets acquired and liabilities assumed in a manner consistent with the accounting model that applies to the transaction. When a transaction is accounted for as an asset acquisition, registrants should keep in mind that R&D costs are only capitalized if the IPR&D asset has an alternative future use. Paragraph 3.14 of the AICPA Guide states that for an asset to have alternative future use, both of the following conditions must be met:

- "[I]t is reasonably expected that the reporting entity will use the asset acquired in the alternative manner and anticipates economic benefit from that alternative use" (footnote omitted).
- The acquired asset "can be used in the alternative manner in the condition in which it existed at the acquisition date."

The determination of whether an acquired intangible asset to be used in R&D activities has an alternative future use depends on specific facts and circumstances. Registrants should carefully consider the specific facts regarding the completed transaction to ensure that they prepare a robust accounting analysis that supports the overall conclusion.

4.2.4.3 Useful Life and Impairment of Intangible Assets

Examples of SEC Comments

- Please explain to us your basis for determining [an X-year] useful life for the currently marketed products rights intangible assets. In your response, tell us the estimated fair value of each such intangible asset acquired, as well as the useful life you assign to each and explain why the assigned life is reasonable. In addition, please tell us why it is appropriate to use straight line amortization, given the likely impact of future competition from branded and generic drug products over this period.
- Please provide us proposed revised disclosure discussing your impairment to be included in your upcoming Form 10-K that provides more insight into what new information was received during the third quarter prompting your impairment charge and reassessment of the useful life of [the product]. In your revised disclosure discuss the general reasons you reassessed the level and timing of [additional] competition.

Examples of SEC Comments (continued)

- Subsequent to the immediate recognition of the license fee [from Customer A], you determined that the license had no future economic value and accelerated the amortization of the remaining balance of this intangible asset . . . . Please provide us additional analysis supporting this accounting treatment. Also elaborate for us on the following factors you noted in your response:
  - [T]he contract term of exclusivity and any termination provisions; and
  - [A] description of current and future market conditions you considered.
- We note you impaired your product rights, developed technologies and IPR&D by $[X] million, $[Y] million and $[Z] million respectively in [the fiscal year]. In order to provide investors with a better understanding of your financial condition and results of operations, please expand your disclosure to separately identify the underlying products or projects that are associated with these impairments . . . , quantify the charge taken, and expand your disclosure to address the underlying causes, including trends, demands, events or uncertainties that gave rise to the impairment.
- Please tell us how you considered the results of the . . . litigation, which was settled prior to the issuance of your most recent Form 10-Q and could potentially negatively impact future sales of [Product A], in assessing your goodwill and intangible assets (including your developed product rights for [Product A]) for potential impairment as of the [end of the fiscal quarter].

Life sciences entities frequently acquire patent rights to approved products in business combinations and asset acquisitions. To determine the useful life of intangible assets, most life sciences companies begin their analysis by considering the patent life of the underlying product (if any). Entities should also consider whether the useful life could be affected by other factors, including, but not limited to, the following:

- Risk of competition.
- High barrier to market entry, including after the entity's patent expires.
- Regulatory or court decisions related to the patent rights.
- Changes to insurance, government reimbursement policies, or both.

In accordance with ASC 350-30-35-4, "[i]f no legal, regulatory, contractual, competitive, economic, or other factors limit the useful life of an intangible asset to the reporting entity, the useful life of the asset shall be considered to be indefinite." In the life sciences industry, finite useful lives are commonly assigned to internally developed or acquired intangible assets that align with the duration of a patent. In contrast, over-the-counter or generic products may have the characteristics of an indefinite-lived intangible asset.

ASC 350-30-35-15 provides that when an entity determines that an intangible asset has an indefinite useful life, the entity should not amortize the asset until it determines that the asset's useful life is no longer indefinite. In accordance with ASC 350-30-35-16, the entity is required to evaluate in each reporting period the remaining useful life of the indefinite-lived intangible asset "to determine whether events and circumstances continue to support an indefinite useful life." If the entity subsequently determines that the asset has a finite useful life, ASC 350-30-35-17 requires the entity to (1) test the asset for impairment in accordance with ASC 350-30-35-18 through 35-19 (i.e., qualitatively and, if necessary, quantitatively) and (2) subsequently amortize the asset "prospectively over its estimated remaining useful life."

ASC 360-10-35-21 provides examples of events or changes in circumstances that management should consider when assessing whether an intangible long-lived asset should be tested for impairment, including a "significant decrease in the market price of [the] long-lived asset," a "significant adverse change in the extent or manner in which [the] long lived asset . . . is being used," and a "significant adverse change in [relevant] legal factors or in the business climate." Life sciences companies may look to other industry-specific indicators when determining whether an intangible asset should be tested for impairment, including:

- Development progression of a competing product (when the company's competitor may be "first to market" or may render the company's product in development obsolete).
- Failure of the drug's efficacy in clinical trials.
- Regulatory rejection of NDAs or ANDAs, with significant findings.
- A change in the economic lives of similar assets.
- Current or expected changes in participation rates, formulary structure, or reimbursement policies of insurance providers.

The SEC staff has asked registrants to provide additional analysis that explains the basis for their conclusions about the useful life of internally developed and acquired intangible assets and how their determination of useful life aligns with the period of economic benefit from the assets. Further, regarding impairment analyses, the staff has required registrants to provide expanded disclosures about their impairment testing policies, including descriptions of (1) the key assumptions used, (2) how the key assumptions are determined, (3) any uncertainties associated with the key assumptions, and (4) any potential events or circumstances that could adversely affect the key inputs to their impairment tests.

4.2.4.4 Contingent Consideration

Examples of SEC Comments

- It appears based on the table of your contingent consideration liability . . . that your liability only includes [an $X million] milestone due [to Company A] upon regulatory approval occurring in March [20XX]. Please tell us why your contingent consideration liability is zero at June 30, [20XX] when you appear to owe [Company A] up to an additional [$X million] in regulatory and sales-based milestones and also owe them royalties of [X]% of future net sales. Reference for us the authoritative literature you rely upon to support your accounting.
- We note that you recorded net income of [$X million] and [$Y million] in [year 3] and [year 2] respectively, due to changes in the fair value of your contingent consideration . . . . Please describe to us the valuation technique and inputs used to determine the fair value as of December 31, [year 1, year 2], and [year 3] and explain to us the reasons for the changes in fair value. Include quantitative information about the significant unobservable inputs used in the fair value measurement. In future filings provide the disclosures required by ASC 820-10-50-2(bbb) and ASC 805-30-50-4.
- Please tell us the unobservable inputs used to fair value your contingent consideration obligation and provide us the quantified information about these inputs as stipulated in ASC 820-10-50-2bbb. Separately tell us your consideration for disclosing this information in your filing.
- You state . . . that you have entered into, and may in the future enter into, agreements that require you to make significant milestone payments. Please disclose the aggregate amount of potential milestone payments and the triggering points of each significant milestone.

Contingent consideration arrangements are common in business combinations and asset acquisitions between life sciences companies. For example, the buyer may owe the seller (1) future development milestones, (2) sales-based milestones, and (3) royalties. Uncertainty associated with these payments arises from a number of factors:

- Before regulatory approval, uncertainty may arise from potential delays with clinical trials, success of competitor trials, or an inability to obtain regulatory approvals.
- After regulatory approval, uncertainty may arise from product safety concerns, manufacturing issues, potential product recalls, the introduction of competitor products, or possible sales and distribution channel issues.

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 in a transaction accounted for as a business combination, 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 the contingent consideration should be reflected as a measurement-period adjustment to the amount of goodwill (i.e., if the adjustment is made because of new information obtained during the measurement period pertaining to 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. Further, the staff may ask for disclosure of the total amount of contingent consideration that could become payable under the terms of the arrangement.

4.2.4.5 Non-GAAP Measures

Examples of SEC Comments

- Describe the nature and purpose of the following non-GAAP adjustments and explain the factors that you considered in excluding them from the non-GAAP financial measures: re-measurement of royalties for medicines acquired through business combinations, drug substance harmonization costs, upfront and milestone payments related to license agreements, accretion of royalty liabilities and royalties for medicines acquired through business combinations.
- We note your non-GAAP adjustment for In-process research and development in the [fiscal third quarter]. We believe the adjustment is inconsistent with Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretation. Please confirm to us you will no longer include the adjustment in any non-GAAP financial measure presented in accordance with Item 10(e) of Regulation S-K or Regulation G.
- We note that you have excluded upfront payments and premiums paid for the acquisition of related common stock to arrive at non-GAAP R&D expense and non-GAAP net income attributable to [Company A]. Please tell us your consideration of the guidance in Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretations for this adjustment. In this regard, you state . . . that in connection with your business strategy, you enter into these collaboration agreements, which are detailed as part of your key business developments on . . . your Form 10-K.

Examples of SEC Comments (continued)

- Please disclose your purpose for including the adjustments for "milestones received from new or existing partners" and "upfront consideration and milestones paid to new or existing partners" in calculating the non-GAAP net income and non-GAAP net income per share measures. Also, tell us how you determined these adjustments do not substitute individually-tailored income or expense recognition methods for those of GAAP. Refer to Question 100.04 of the Division's Non-GAAP Financial Measures Compliance and Disclosure Interpretations.
- In your determination of net earnings . . . on a non-GAAP basis, you exclude "R&D charges or other income resulting from upfront or contingent milestone payments in connection with the acquisition or licensing of third-party intellectual property rights." In this regard, your statement that "similar charges or gains were recognized in prior periods and will likely occur in future periods" appears to indicate that these R&D charges are inherently recurring in nature. Please explain the factors that you considered in concluding that exclusion of these charges complied with Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretations. Revise your non-GAAP presentation accordingly.

The SEC staff has continued to evaluate the form of preparers' non-GAAP disclosures in the context of its C&DIs. Recently, the staff has focused more acutely on the appropriateness and usefulness of the metrics presented and the nature and description of the adjustments included therein. For example, some companies in the life sciences industry make adjustments for up-front, milestone, and royalty payments made to or received from other parties to business development transactions, including collaborative arrangements and the acquisition or licensing of third-party IP rights. The SEC staff has commented on the nature and purpose of these adjustments and has sometimes informed registrants that they should no longer include these adjustments in their non-GAAP financial measures because, in the staff's view, costs related to these arrangements are recurring or are a normal part of business activities or strategies of such registrants.

For additional discussion of non-GAAP comment letter trends, see Deloitte's Roadmap *SEC Comment Letter Considerations, Including Industry Insights*.

4.2.5 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, there has been diversity in practice related to the treatment of contingent consideration. Note that the accounting policy considerations discussed below are relevant only to groups of assets that meet the definition of a business. For considerations related to the sale of assets, see Section 2.2.3, which discusses the accounting for asset dispositions under the revenue standard, including the need, under certain circumstances, to record variable consideration associated with an asset disposition that otherwise is not considered a revenue activity.

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.

In arrangements in which the payment is determined to be contingent consideration (i.e., not separate transactions), the seller should determine whether the arrangement meets the definition of a derivative instrument. If the arrangement meets the definition of a derivative, it should be accounted for under ASC 815. For contingent consideration arrangements that do not meet the definition of a derivative, the entity may consider the discussions related to EITF Issue No. 09-4. At the EITF's meeting on September 9–10, 2009, the Task Force considered two approaches 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, diversity in practice related to a seller's accounting for a contingent consideration arrangement may continue. Nevertheless, entities should establish an accounting policy for the initial and subsequent measurement of this type of arrangement. 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.

The two approaches considered by the EITF are as follows:

- *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 4-17

Parent A has a wholly owned subsidiary that represents a business and has 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	30	—
Total consideration	180	150
Less: subsidiary's carrying amount	(100)	(100)
Initial gain on sale	$ 80	$ 50

4.2.6 Reverse Acquisitions

A reverse acquisition is a common type of business combination in the life sciences industry. A reverse acquisition occurs when the entity that issues its shares or gives other consideration to effect the transaction is determined for accounting purposes to be the acquiree (also called the accounting acquiree or legal acquirer), while the entity whose shares are acquired is for accounting purposes the acquirer (also called the accounting acquirer or legal acquiree). The accounting acquiree/legal acquirer generally continues in existence as the legal entity whose shares represent the outstanding common shares of the combined company. While the accounting acquiree/legal acquirer continues to issue its own financial statements, those statements are often in the name of the accounting acquirer/legal acquiree because the legal acquirer often adopts the name of the legal acquiree. The financial reporting reflects the accounting acquirer's/legal acquiree's financial information, except for its equity, which is retroactively adjusted to reflect the equity of the accounting acquiree/legal acquirer.

Example 4-18

Company A, a public company with substantive operations and a December 31 year-end, has 1 million common shares outstanding as of June 30, 20X9. On July 1, 20X9, in a transaction accounted for as a business combination, A issues 4 million of its newly registered common shares to Company B, a private entity, in exchange for all of B's 2 million outstanding common shares (an exchange rate of 2:1). After the transaction, B controls A's voting rights through its 80 percent ownership interest (4 million common shares held ÷ 5 million total common shares outstanding) and its ability to elect the majority of the combined entity's board members.

Although A issued common shares to effect the business combination, B would be considered the accounting acquirer under ASC 805, provided that there are no other existing pertinent facts and circumstances to the contrary after consideration of the factors in ASC 805-10-55-12 through 55-14.

For more information about how to account for reverse acquisitions, see Section 6.8 of Deloitte's Roadmap *Business Combinations*.

4.2.6.1 Reverse Acquisition of a Public Company by a Private Company

As an alternative to undertaking a traditional IPO as a means of becoming a public company, it has become common in the life sciences industry for a private company to acquire a public company through a reverse acquisition. Often, the public company has failed clinical trials for one or more R&D projects. In a typical reverse acquisition of a public company by a private company:

- The private company is legally acquired by the public company.
- The preacquisition stockholders of the private company own a majority of the voting stock of the combined postacquisition company.
- The management and other key employees of the private company become the management and key employees of the combined postacquisition company.
- The composition of the combined postacquisition company's board of directors reflects representation proportional to the postacquisition ownership split of the voting stock.
- The business operations of the private company become the business operations of the public company.
- The combined postacquisition company changes its name to the name of the private company.

In a reverse acquisition, one of the key accounting judgments is the determination of which entity is the accounting acquirer. ASC 805-10-25-4 requires entities to identify an acquirer in every business combination. The ASC master glossary defines an acquirer as follows:

> The entity that obtains control of the acquiree. However, in a business combination in which a variable interest entity (VIE) is acquired, the primary beneficiary of that entity always is the acquirer.

If the legal acquiree in a business combination is a VIE, the primary beneficiary of the VIE is considered the accounting acquirer in accordance with the guidance in ASC 805-10-25-5. Consequently, entities must consider whether the legal acquiree is a VIE on the basis of the guidance in ASC 810-10-15-14. If a private life sciences company is deemed to be the legal acquiree and a VIE, the entity that is the primary beneficiary of the VIE is the accounting acquirer. Because of the judgment involved in the determination of whether the private company is a VIE, including the evaluation of the sufficiency of equity as required under ASC 810-10-15-14(a), discussion with accounting advisers is encouraged.

If the acquiree in a business combination is a voting interest entity rather than a VIE, entities should first consider the guidance in the general subsections of ASC 810-10 related to determining the existence of a controlling financial interest to identify the accounting acquirer. In many cases, entities can clearly identify the accounting acquirer by applying that guidance. If they cannot, the identification of the accounting acquirer should be based on an evaluation of "pertinent facts and circumstances." ASC 805-10-55-11 through 55-15 provide guidance to assist in this evaluation. In a business combination effected primarily by exchanging equity interests, the identification of the accounting acquirer is based on an evaluation of pertinent facts and circumstances, including the following:

- "The relative voting rights in the combined entity after the business combination" (ASC 805-10-55-12(a)).
- "The existence of a large minority voting interest in the combined entity" (ASC 805-10-55-12(b)).
- "The composition of the governing body of the combined entity" (ASC 805-10-55-12(c)).
- "The composition of the senior management of the combined entity" (ASC 805-10-55-12(d)).
- "The terms of the exchange of equity interests" (ASC 805-10-55-12(e)).

- The relative size of the combining entities (ASC 805-10-55-13).
- Other considerations.

Further, if the private company is determined to be the accounting acquirer of the public company, the transaction could be accounted for as:

- A reverse recapitalization of the private company if the public company's assets represent only net monetary assets such as cash.
- A reverse asset acquisition if the public company's net assets acquired do not meet the definition of a business under ASC 805.
- A reverse acquisition if the public company's net assets acquired meet the definition of a business under ASC 805.

See Section 3.1 of Deloitte's Roadmap *Business Combinations* for more information about identifying the acquirer. Because of the judgment involved, discussion with accounting advisers is encouraged.

4.3 New Accounting Standard — Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities From Contracts With Customers (ASU 2021-08)

4.3.1 Background

In October 2021, the FASB issued ASU 2021-08, which amends ASC 805 to "require acquiring entities to apply Topic 606 to recognize and measure contract assets and contract liabilities in a business combination." Under current GAAP, an acquirer generally recognizes such items at fair value on the acquisition date.

The ASU's stated purpose is "to improve the accounting for acquired revenue contracts with customers in a business combination by addressing diversity in practice and inconsistency related to the following:

1. Recognition of an acquired contract liability
2. Payment terms and their effect on subsequent revenue recognized by the acquirer."

The ASU further notes that its amendments will:

- "[I]mprove comparability for both the recognition and measurement of acquired revenue contracts with customers at the date of and after a business combination."
- "[I]mprove comparability by specifying for all acquired revenue contracts regardless of their timing of payment (1) the circumstances in which the acquirer should recognize contract assets and contract liabilities that are acquired in a business combination and (2) how to measure those contract assets and contract liabilities."
- "[I]mprove comparability after the business combination by providing consistent recognition and measurement guidance for revenue contracts with customers acquired in a business combination and revenue contracts with customers not acquired in a business combination."

4.3.2 Key Provisions

ASU 2021-08 amends ASC 805 to add contract assets and contract liabilities to the list of exceptions to the recognition and measurement principles that apply to business combinations and to "require that an entity (acquirer) recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606." While primarily related to contract assets and contract liabilities that were accounted for by the acquiree in accordance with ASC 606, "the amendments also apply to contract assets and contract liabilities from other contracts to which the provisions of Topic 606 apply, such as contract liabilities from the sale of nonfinancial assets within the scope of Subtopic 610-20."

As a result of the amendments made by the ASU, it is expected that an acquirer will generally recognize and measure acquired contract assets and contract liabilities in a manner consistent with how the acquiree recognized and measured them in its preacquisition financial statements.

For more information about ASU 2021-08, including its practical expedients, see Deloitte's November 2, 2021, *Heads Up* and Section 4.3.13 of Deloitte's Roadmap *Business Combinations*.

4.3.3 Effective Dates and Transition

The effective dates of ASU 2021-08 are as follows:

- For PBEs, fiscal years beginning after December 15, 2022, including interim periods within those fiscal years.
- For all other entities, fiscal years beginning after December 15, 2023, including interim periods within those fiscal years.

The ASU's amendments should be applied prospectively to business combinations occurring on or after the effective date of the amendments.

The ASU clarifies that "[e]arly adoption of the amendments is permitted, including adoption in an interim period. An entity that early adopts in an interim period should apply the amendments (1) retrospectively to all business combinations for which the acquisition date occurs on or after the beginning of the fiscal year that includes the interim period of early application and (2) prospectively to all business combinations that occur on or after the date of initial application." For example, assume that an entity with a calendar year-end had one business combination in the second quarter of 2020 and another business combination in the third quarter of 2021. If the entity adopted the amendments in the fourth quarter of 2021, it would apply the amendments retrospectively to the acquisition that occurred in the third quarter of 2021 but would not apply the amendments retrospectively to the acquisition that occurred in the second quarter of 2020 even if it had not yet issued financial statements for the year ended December 31, 2020.

Appendix B — Titles of Standards and Other Literature

AICPA Literature

Accounting and Valuation Guides

Assets Acquired to Be Used in Research and Development Activities

Valuation of Privately-Held-Company Equity Securities Issued as Compensation

Clarified Statements on Auditing Standards

AU-C Section 501, "Audit Evidence — Specific Considerations for Selected Items"

AU-C Section 620, "Using the Work of an Auditor's Specialist"

FASB Literature

ASC Topics

ASC 105, *Generally Accepted Accounting Principles*

ASC 205, *Presentation of Financial Statements*

ASC 210, *Balance Sheet*

ASC 220, *Income Statement — Reporting Comprehensive Income*

ASC 230, *Statement of Cash Flows*

ASC 235, *Notes to Financial Statements*

ASC 250, *Accounting Changes and Error Corrections*

ASC 260, *Earnings per Share*

ASC 270, *Interim Reporting*

ASC 275, *Risks and Uncertainties*

ASC 280, *Segment Reporting*

ASC 310, *Receivables*

ASC 320, *Investments — Debt Securities*

ASC 321, *Investments — Equity Securities*

ASC 323, *Investments — Equity Method and Joint Ventures*

ASC 326, *Financial Instruments — Credit Losses*

ASC 330, *Inventory*

ASC 340, *Other Assets and Deferred Costs*

ASC 350, *Intangibles — Goodwill and Other*

ASC 360, *Property, Plant, and Equipment*

ASC 405, *Liabilities*

ASC 410, *Asset Retirement and Environmental Obligations*

ASC 420, *Exit or Disposal Cost Obligations*

ASC 440, *Commitments*

ASC 450, *Contingencies*

ASC 460, *Guarantees*

ASC 470, *Debt*

ASC 480, *Distinguishing Liabilities From Equity*

ASC 505, *Equity*

ASC 605, *Revenue Recognition*

ASC 606, *Revenue From Contracts With Customers*

ASC 610, *Other Income*

ASC 705, *Cost of Sales and Services*

ASC 710, *Compensation — General*

ASC 712, *Compensation — Nonretirement Postemployment Benefits*

ASC 715, *Compensation — Retirement Benefits*

ASC 718, *Compensation — Stock Compensation*

ASC 720, *Other Expenses*

ASC 730, *Research and Development*

ASC 740, *Income Taxes*

ASC 805, *Business Combinations*

ASC 808, *Collaborative Arrangements*

ASC 810, *Consolidation*

ASC 815, *Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 830, *Foreign Currency Matters*

ASC 832, *Government Assistance*

ASC 835, *Interest*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 845, *Nonmonetary Transactions*

ASC 848, *Reference Rate Reform*

ASC 855, *Subsequent Events*

ASC 860, *Transfers and Servicing*

ASC 905, *Agriculture*

ASC 915, *Development Stage Entities*

ASC 930, *Extractive Activities — Mining*

ASC 944, *Financial Services — Insurance*

ASC 946, *Financial Services — Investment Companies*

ASC 948, *Financial Services — Mortgage Banking*

ASC 954, *Health Care Entities*

ASC 958, *Not-for-Profit Entities*

ASC 960, *Plan Accounting — Defined Benefit Pension Plans*

ASC 970, *Real Estate — General*

ASC 985, *Software*

ASUs

ASU 2010-27, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers* — a consensus of the FASB Emerging Issues Task Force

ASU 2011-06, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers* — a consensus of the FASB Emerging Issues Task Force

ASU 2014-09, *Revenue From Contracts With Customers (Topic 606)*

ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810,* Consolidation

ASU 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*

ASU 2014-16, *Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity* — a consensus of the FASB Emerging Issues Task Force

ASU 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*

ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

ASU 2016-02, *Leases (Topic 842)*

ASU 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing*

ASU 2016-12, *Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*

ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*

ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* — a consensus of the FASB Emerging Issues Task Force

ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*

ASU 2016-17, *Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control*

ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* — a consensus of the FASB Emerging Issues Task Force

ASU 2016-20, *Technical Corrections and Improvements to Topic 606,* Revenue From Contracts With Customers

ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*

ASU 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*

ASU 2017-11, *Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception*

ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*

ASU 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*

ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*

ASU 2018-10, *Codification Improvements to Topic 842,* Leases

ASU 2018-11, *Leases (Topic 842): Targeted Improvements*

ASU 2018-17, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*

ASU 2019-01, *Leases (Topic 842): Codification Improvements*

ASU 2019-04, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses*, Topic 815,* Derivatives and Hedging*, and Topic 825,* Financial Instruments

ASU 2019-05, *Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief*

ASU 2019-10, *Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*

ASU 2019-11, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses

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Appendix C — Abbreviations

Abbreviation	Description
AETR	annual effective tax rate
AFS	available for sale
AFSI	adjusted financial statement income
AI	artificial intelligence
AICPA	American Institute of Certified Public Accountants
AIN	AICPA Accounting Interpretation of an APB Opinion
AMT	alternative minimum tax
ANDA	abbreviated new drug application
APB	Accounting Principles Board
API	active pharmaceutical ingredient
ARO	asset retirement obligation
ASC	FASB Accounting Standards Codification
ASR	accelerated share repurchase
ASU	FASB Accounting Standards Update
AUD	Australian dollar
BCF	beneficial conversion feature
BEAT	base erosion anti-abuse tax
BEMTA	base erosion minimum tax amount
BPD	branded prescription drug
C&DIs	Compliance and Disclosure Interpretations
CAM	critical audit matter
CAQ	Center for Audit Quality
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CCF	cash conversion feature

Abbreviation	Description
CECL	current expected credit loss
CFC	controlled foreign corporation
CIMA	Chartered Institute of Management Accountants
CMO	contract manufacturing organization
CRO	contract research organization
CSRD	Corporate Sustainability Reporting Directive
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
ED	exposure draft
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EGC	emerging growth company
EITF	Emerging Issues Task Force
ELOC	equity line of credit
EPS	earnings per share
ESA	energy service agreement
ESG	environmental, social, and governance
ESPP	employee stock purchase plan
ESRS	European Sustainability Reporting Standards
EUR	euros
Exchange Act	Securities Exchange Act of 1934
FASB	Financial Accounting Standards Board
FAST Act	Fixing America's Surface Transportation Act

Abbreviation	Description
FDA	U.S. Food and Drug Administration
FDII	foreign-derived intangible income
FOB	free on board
FPI	foreign private issuer
FRM	SEC Division of Corporation Finance Financial Reporting Manual
FVO	fair value option
FVTOCI	fair value through other comprehensive income
GAAP	generally accepted accounting principles
GenAI	generative artificial intelligence
GHG	greenhouse gas
GILTI	global intangible low-taxed income
GloBE	Global anti-Base Erosion
GPO	group purchasing organization
HAFWP	how and for what purpose
HFI	held for investment
HFS	held for sale
HVAC	heating, ventilation, and air conditioning
IAS	International Accounting Standard
IASB	International Accounting Standards Board
IBNR	incurred but not reported
ICFR	internal control over financial reporting
IFRIC	IFRS Interpretations Committee
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research
IP	intellectual property
IPO	initial public offering
IPR&D	in-process research and development
IRC	Internal Revenue Code
IRS	Internal Revenue Service
ISO	incentive stock option

Abbreviation	Description
ISSB	International Sustainability Standards Board
IT	information technology
ITC	invitation to comment
JOBS Act	Jumpstart Our Business Startups Act
LCD	liquid-crystal display
LIBOR	London Interbank Offered Rate
LIFO	last in, first out
M&A	merger and acquisition
MD&A	Management's Discussion & Analysis
MNE	multinational enterprise
MSL	medical science liaison
NDA	new drug application
NFP	not-for-profit (entity)
NIH	National Institutes of Health
NOL	net operating loss
NOPA	notice of proposed adjustment
NQSO or **NSO**	nonqualified stock option
OCA	SEC's Office of the Chief Accountant
OCI	other comprehensive income
OECD	Organisation for Economic Co-operation and Development
OEM	original equipment manufacturer
PBE	public business entity
PCAOB	Public Company Accounting Oversight Board
PCC	Private Company Council
PIPE	private investment in public equity
PP&E	property, plant, and equipment
PRV	priority review voucher
PTRS	probability of technical and regulatory success
Q&A	question and answer
QIP	qualified improvement property

Abbreviation	Description
R&D	research and development
R&E	research and experimental
REC	renewable energy certificate
REMS	risk evaluation and mitigation strategy
RIM	retail inventory method
ROU	right of use
SaaS	software as a service
SAB	Staff Accounting Bulletin
SEC	U.S. Securities and Exchange Commission
Securities Act	Securities Act of 1933
SEPA	standby equity purchase agreement
SOX	Sarbanes-Oxley Act of 2002
SPAC	special-purpose acquisition company
SPPI	solely payments of principal and interest
SRC	smaller reporting entity
S&P 500	Standard & Poor's 500 Index
TD	Treasury Decision
TDR	troubled debt restructuring
TRG	transition resource group
TRWG	IFRS Foundation Technical Readiness Working Group
TSA	transition services agreement
USD	U.S. dollars
UTB	unrecognized tax benefit
VIE	variable interest entity
VWAP	volume-weighted average daily market price
XBRL	eXtensible Business Reporting Language

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