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*Equity Method Investments and Joint Ventures*
*Equity Method Investees — SEC Reporting Considerations*
*Foreign Currency Transactions and Translations*
*Income Taxes*
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*Non-GAAP Financial Measures*
*Revenue Recognition*
*SEC Comment Letter Considerations, Including Industry Insights*
*Segment Reporting*
*Share-Based Payment Awards*
*Statement of Cash Flows*

**Coming soon:**
*Convertible Debt*
Acknowledgments and Contact Information

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Preface

March 2019

To our clients, colleagues, and other friends:

The life sciences industry represents entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and medical 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 industry face complex issues and must exercise significant judgment in applying existing rules related to research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. This publication, our 10th annual accounting and financial reporting update for the life sciences industry, addresses these and other topics affecting the industry in 2019. It includes updated interpretive guidance as well as new sections that discuss initial public offerings (IPOs), accounting considerations for health technology companies, and the latest developments in standard setting. In addition, this publication discusses the outlook for the life sciences industry in 2019.

Appendix A lists the titles of standards and other literature we cited, and Appendix B defines the abbreviations we used.

This publication is available on US GAAP Plus and the Deloitte Accounting Research Tool (DART).

We hope this publication helps you navigate the various accounting and reporting challenges you face. We encourage you to contact your Deloitte team for additional information and assistance.

Sincerely,

Jeff Ellis       Dennis Howell
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Chapter 1 — 2019 Industry Outlook
Summary

Trends in life sciences generally evolve over decades, but many foundational elements that could signal the sector’s future are taking shape in 2019. Consider, for example, the shift from treatment to wellness, pricing pressures, digital technology expansion, and increased use of omics and real-world data. Also making their mark are ongoing breakthroughs in the fundamental science behind therapies and cures, the incorporation of the patient voice throughout the life cycle of therapy development, and new nontraditional partnerships.

Here are four trends for life sciences organizations to monitor in 2019:

- **Scrutinizing drug pricing** — The year 2018 saw policy efforts to reduce drug prices and out-of-pocket expenses for patients. In April 2018, the White House and the U.S. Department of Health and Human Services released a blueprint for lowering drug prices, reducing out-of-pocket costs for consumers, and making drugs more accessible. Topics of focus included proposed changes related to the International Pricing Index for Medicare Part B drugs, the 340B drug pricing program, and requirements that drugmakers include list prices in their direct-to-consumer ads.

- **Increasing interest in contracts that demonstrate value** — The launch of several gene and cell therapies has advanced discussions of alternative payment models. As health plans embrace more value-based contracts, life sciences companies are likely to develop pricing strategies that demonstrate the long-term benefits of their products.

- **Declining return on investment (ROI) for R&D** — A Deloitte analysis on the ROI of R&D among 12 large-cap biopharma companies portrays a steep decline during the years we have performed the analysis. Our 2018 analysis found that R&D returns declined to 1.9 percent, down from 10.1 percent in 2010 — the lowest level in nine years.

- **Evolving regulatory frameworks and collaboration between industry and regulators** — The U.S. Food and Drug Administration’s (FDA’s) precertification program, which launched in late 2017, demonstrates how collaboration between industry and regulators can drive more self-regulation rooted in quality, organizational excellence, and performance monitoring. As software-based medical products mature, feedback provided during the pilot will help the FDA refine the proposed regulatory model and could influence new regulations and guidelines and address outstanding issues. The FDA has indicated that it intends to collaborate with companies to bring innovations to market more quickly. In addition to its software as a medical device pilot, the FDA has supported increased use of real-world data and approved many innovative therapies over the past year. Collaboration may enable more proactive, cost-effective care and improved outcomes.
In response to these trends, life sciences companies can prepare for a future grounded in digital, data, personalization, and efficiency by doing the following:

- **Embracing a digital-first mind-set** — Digital technology could change everything from the way R&D is conducted to how clinical trials are designed to how new products are commercialized. But many companies are still experimenting and are reluctant to make bold moves, according to a survey of biopharma executives that we conducted with the *MIT Sloan Management Review*. A digital-first mind-set is increasingly essential to making business operations more efficient and bringing transformational therapies to market. The industry will most likely continue to adopt technologies such as robotic process automation — which can help improve the efficiency of R&D, including clinical trials — as well as cognitive, artificial intelligence, and real-world data.

More companies may also hire digital talent from the outside. There appears to be an expectation that digitally savvy outsiders can offer a fresh perspective to typically conservative life sciences companies. Case in point: global pharmaceutical manufacturer Merck recently hired its first chief digital and information officer, whose most recent experience was with consumer product companies, including Nike Inc. In addition, Novartis’s chief digital officer (CDO) was previously the CDO at one of the United Kingdom’s largest online retailers and also held senior positions at Amazon.com.

- **Using new forms of data to demonstrate value** — The targeted nature of precision medicine could mean better patient outcomes in an increasing number of therapeutic areas — particularly if digital tools can help ensure that patients comply with their treatment regimens, monitor the effectiveness of therapies, and report adverse events. With outcomes-based and alternative payment models being piloted, life sciences companies are likely to focus on multiple external data sources that may drive disruption across the entire value chain, from R&D to the delivery of care to regulatory review and approvals.

Real-world data may be key to creating new business models by (1) using patient outcomes to support value-based contracts for personalized medications or (2) using information from wearable devices to understand and improve the patient journey. According to our real-world evidence benchmarking survey, however, companies have not fully unlocked the potential: only half of surveyed companies have capabilities mature enough to take full advantage. With the business value now better understood, more life sciences companies will align with real-world data strategies in 2019 as they prepare for a new future.

- **Collaborating with new partners** — 2018 was a big year for nontraditional competitors and technology companies entering the market. One of the more significant market signals was Roche’s acquisition of Flatiron Health last year, pointing to a focus on big data, analytics, and personalized medicine. We have historically seen life sciences companies partner with providers and academia, but we expect more nontraditional acquisitions and partnerships in 2019 to drive innovation and patient-focused agendas. For example, there may be more partnerships between life sciences companies and patient advocacy organizations, informatics companies, or technology firms to improve the design and delivery of therapies. The Internet of Medical Things may also lead to interesting partnerships as companies focus on connected devices.

- **Finding new ways to connect with consumers** — Advancements in electronic health records are paving the way for consumers to take more active roles in their health and wellness. While some consumers still might be leery of this concept, our 2018 health care consumer survey revealed a willingness to embrace new tools and technologies. The challenge will be in creating intrinsic value for consumers and ultimately winning their trust (the same survey told us that
consumers are less likely to share their data with life sciences companies than with other health-related organizations). Technology could help bridge the gap and make clinical trials and other connection points more patient-friendly and accessible. More at-home diagnostics are also likely to enter the market this year, and the resulting data may drive more proactive health care and help companies better understand their patients.

2019 could be a foundational year for change as companies continue to focus on wellness in addition to treatment and on adding value to the overall health care system, setting the stage for the future of life sciences and health care.

For a detailed analysis of the opportunities and challenges facing life sciences companies, see the full version of Deloitte’s 2019 Global Life Sciences Sector Outlook.
Chapter 2 — Revenue Recognition

2.1 Introduction

In May 2014, the FASB and the International Accounting Standards Board (IASB®) issued their final standard on revenue from contracts with customers. The standard, issued by the FASB as ASU 2014-09 (codified primarily in ASC 606) and by the IASB as IFRS 15, outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance.

Upon issuing the new revenue standard, the FASB and IASB formed a joint revenue transition resource group (TRG). The purpose of the TRG is not to issue guidance but instead to seek and provide feedback on potential issues related to implementation of the new revenue standard. By analyzing and discussing potential implementation issues, the TRG has helped the boards determine whether to take additional action, such as providing clarification or issuing other guidance.

Largely as a result of feedback provided by the TRG after the issuance of the initial ASU, the FASB issued the following ASUs to amend and clarify the guidance in the new revenue standard:

- **ASU 2015-14** on deferral of the effective date.
- **ASU 2016-08** on principal-versus-agent considerations (reporting revenue gross versus net).
- **ASU 2016-10** on identifying performance obligations and licensing.
- **ASU 2016-11** on rescission of certain SEC guidance because of ASUs 2014-09 and 2014-16.
- **ASU 2016-12** on narrow-scope improvements and practical expedients.
- **ASU 2016-20** on technical corrections and improvements.
- **ASU 2017-05** on clarifying the scope of asset derecognition guidance and accounting for partial sales of nonfinancial assets.
- **ASU 2018-08** on clarifying the scope and the accounting guidance for contributions received and contributions made.
- **ASU 2018-18** on clarifying the interaction between ASC 808 and ASC 606.
In addition to the above ASUs, life sciences entities should be aware of various pronouncements and activities of the SEC staff, including the following:

- **SEC staff announcement at the July 20, 2017, EITF meeting** — The SEC staff provided significant relief to registrants that are required to include financial statements or financial information of other reporting entities in their SEC filings. Specifically, as reported in the minutes of the EITF meeting, the SEC staff announced that it would not object to elections by certain public business entities (PBEs) to use the non-PBE effective dates for the sole purpose of adopting the FASB’s new standards on revenue (ASC 606) and leases (ASC 842). The staff announcement makes clear that the ability to use non-PBE effective dates for adopting the new revenue and leases standards is limited to the subset of PBEs “that otherwise would not meet the definition of a public business entity except for a requirement to include or the inclusion of its financial statements or financial information in another entity’s filing with the SEC” (referred to herein as “specified PBEs”).

While the staff announcement is written in the context of specified PBEs, the principal beneficiaries of the relief will be SEC filers that include financial statements or financial information prepared by specified PBEs in their own filings, for example, under the following SEC Regulation S-X rules:

- Rule 3-05, “Financial Statements of Businesses Acquired or to Be Acquired.”
- Rule 3-09, “Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons.”
- Rule 3-14, “Special Instructions for Real Estate Operations to Be Acquired.”
- Rule 4-08(g), “Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons.”

In September 2017, the FASB issued **ASU 2017-13**, which codifies in ASC 606-10-S65-1 the SEC staff announcement. See Deloitte’s July 20, 2017, **Heads Up** for more information about the definition of a PBE.

- **The August 18, 2017, release of SAB 116** — SAB 116 provides that SAB Topic 13 will no longer be applicable when a registrant adopts ASC 606 since ASC 606 “eliminates the need for [SAB] Topic 13.” In addition, SAB 116 modifies SAB Topic 11.A to clarify that “revenues from operating-differential subsidies presented under a revenue caption should be presented separately from revenue from contracts with customers accounted for under [ASC] 606.” In November 2017, the FASB issued **ASU 2017-14**, which rescinds certain SEC staff guidance in light of SAB 116. For more information about SAB 116, see Deloitte’s August 22, 2017, **journal entry**.

ASU 2014-09 states that the core principle of the new revenue recognition guidance is that an “entity shall recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.” The ASU indicates that an entity should perform the following five steps in recognizing revenue:

- “Identify the contract(s) with a customer” (step 1).
- “Identify the performance obligations in the contract” (step 2).
- “Determine the transaction price” (step 3).
- “Allocate the transaction price to the performance obligations in the contract” (step 4).
- “Recognize revenue when (or as) the entity satisfies a performance obligation” (step 5).
The graphic below summarizes the five-step model for recognizing revenue under ASC 606:

1. Identify the contract with a customer
2. Identify the performance obligations
3. Determine the transaction price
4. Allocate the transaction price
5. Recognize revenue when (or as) performance obligations are satisfied

- A contract is an agreement between two or more parties that creates enforceable rights and obligations.
- A contract can be written, oral, or implied by an entity's customary business practices.
- For a contract to exist under ASC 606, the following five criteria must be met:
  - The parties to the contract have approved the contract.
  - The entity can identify each party's rights.
  - The entity can identify the payment terms.
  - The contract has commercial substance.
  - It is probable that the entity will collect the amount to which it expects to be entitled.
- A performance obligation is the promise to transfer to the customer a good or service (or bundle of goods or services) that is distinct.
- Distinct goods and services should be accounted for as separate units of account.
- Entities need to determine whether a good or service (or bundle of goods or services) is "capable of being distinct" and "distinct in the context of the contract."
- A series of substantially the same goods or services for which control transfers over time and that have the same pattern of transfer is accounted for as a single performance obligation.
- The transaction price is the amount the entity expects to be entitled to in exchange for transferring promised goods or services to the customer.
- The transaction price may include fixed amounts, variable amounts, or both.
- To determine the transaction price, entities should consider the effects of:
  - Variable consideration.
  - The constraint on estimates of variable consideration.
  - Significant financing components.
  - Noncash consideration.
  - Consideration payable to the customer.
- The transaction price (from step 3) is allocated to each performance obligation identified (from step 2).
- On the basis of its specific circumstances, an entity would use one of the following approaches to allocate the transaction price to the performance obligations:
  - Allocate according to each performance obligation's stand-alone selling price.
  - Allocate a discount or variable amount to a specific performance obligation (or bundle of specific performance obligations) if certain criteria are met.
- Requires consideration of:
  - Revenue recognition when (or as) control of the good or service is passed to the customer.
  - The criteria for satisfying performance obligations and recognizing revenue over time.
  - Measurement of progress toward satisfying performance obligations to determine a pattern of revenue recognition over time.
  - Indicators of when performance obligations are satisfied and when to recognize revenue at a point in time.

In addition, ASU 2014-09 requires significantly expanded disclosures about revenue recognition, including both quantitative and qualitative information about (1) the amount, timing, and uncertainty of revenue (and related cash flows) from contracts with customers; (2) the judgment, and changes in judgment, exercised in the application of the new revenue standard; and (3) the assets recognized from costs to obtain or fulfill a contract with a customer.
The sections below discuss some of the key accounting considerations under the new revenue standard for life sciences entities. For more detailed information about the new revenue standard, see Deloitte’s *A Roadmap to Applying the New Revenue Recognition Standard* (the “Revenue Roadmap”) and its TRG Snapshot series. See also Deloitte’s September 26, 2018, *Heads Up* for a discussion of key SEC comment letter themes related to accounting and disclosure requirements associated with the application of ASC 606 and Deloitte’s May 9, 2017, *Heads Up* for considerations related to a company’s internal control over financial reporting in connection with its adoption of the new revenue standard.

2.2 Scope
The new revenue standard applies to all contracts with customers as defined in the standard except those that are within the scope of other topics in the *FASB Accounting Standards Codification*. For example, the new revenue standard does not apply to contracts within the scope of ASC 840 and ASC 842 (leases). In addition, certain provisions in the new revenue standard also apply to transfers of nonfinancial assets, including in-substance nonfinancial assets that are not an output of an entity’s ordinary activities (e.g., intangible assets such as intellectual property (IP) rights). Such provisions include guidance on recognition (including determining the existence of a contract and control principles) and measurement.

Some of the more common issues that life sciences entities have faced when considering the scope of the new revenue standard are discussed below.

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

Collaborative arrangements frequently involve activities such as R&D, regulatory activities, manufacturing, distribution, sales and marketing activities, and general and administrative tasks. Often, a governance structure (e.g., a joint steering committee) is established to facilitate decision-making during the terms of the endeavor. In collaborations, the parties may allocate responsibility for individual activities to each other or share the responsibility for one or more activities under a joint operating arrangement. Joint operating activities may involve the joint development and ultimate commercialization of IP related to a potential new drug candidate, R&D, marketing (including promotional activities and physician detailing), general and administrative activities, manufacturing, and distribution activities. On the basis of contractually defined terms, the participants share in the profits or losses associated with these joint activities.

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

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

Upon entering into a collaborative arrangement, the participants frequently exchange up-front license fees and agree to subsequent payments based on the achievement of milestones during drug development, as well as future royalties and profit- or loss-sharing provisions.
**Q&A 2-1 Applicability of the New Revenue Standard to the Parties of a Collaborative Arrangement (Before the Adoption of ASU 2018-18)**

**Question**

Does the new revenue standard apply to the parties of a collaborative arrangement?

**Answer**

It depends. The new revenue standard applies to all contracts with customers. ASC 606-10-15-3 defines a customer as “a party that has contracted with an entity to obtain goods or services that are an output of the entity’s ordinary activities in exchange for consideration.” However, that provision also notes that a “counterparty to the contract would not be a customer if, for example, the counterparty has contracted with the entity to participate in an activity or process in which the parties to the contract share in the risks and benefits that result from the activity or process (such as developing an asset in a [collaborative] arrangement) rather than to obtain the output of the entity’s ordinary activities.”

The Background Information and Basis for Conclusions of ASU 2014-09 explains that the relationship between a customer and a vendor varies from industry to industry and that companies will therefore have to consider their own facts and circumstances to determine who is a customer in an arrangement. For many contracts, this will not be very difficult to determine; however, paragraph BC54 of ASU 2014-09 provides examples of arrangements in which the facts and circumstances would have to be assessed, including “[c]ollaborative research and development efforts between biotechnology and pharmaceutical entities or similar arrangements in the aerospace and defense, technology, and healthcare industries, or in higher education.”

The example below illustrates how an entity would determine whether an arrangement is a collaborative arrangement and, if so, whether it should be accounted for under ASC 606.

**Example**

Biotech B and Pharma P enter into an agreement to research, develop, and commercialize drug X. Biotech B will perform the R&D, and Pharma P will commercialize the drug. Both parties agree to participate equally in all activities that result from the research, development, and commercialization. The reporting entity concludes that a collaborative arrangement exists because both parties are active participants and have agreed to share in the risks and rewards.

Despite this conclusion, however, there still could be a vendor/customer relationship as a result of some of the activities between the participants pursuant to the collaborative arrangement. If such a relationship exists, those parts of the contract that are related to the vendor/customer relationship may need to be accounted for under ASC 606.
Chapter 2 — Revenue Recognition

**Connecting the Dots**

ASC 606 does not change the guidance in ASC 808 on the income statement presentation, classification, and disclosures applicable to collaborative arrangements within the scope of the new revenue standard. It is important to understand that a contract could be within the scope of both the new revenue standard and the guidance on collaborative agreements, as indicated in paragraph BC55 of ASU 2014-09:

The Boards noted that a contract with a collaborator or a partner (for example, a joint arrangement as defined in IFRS 11, *Joint Arrangements*, or a collaborative arrangement within the scope of Topic 808, *Collaborative Arrangements*) also could be within the scope of Topic 606 if that collaborator or partner meets the definition of a customer for some or all of the terms of the arrangement.

This is important because companies may have to assess the scope of both ASC 606 and ASC 808 for these types of arrangements. In addition, the Background Information and Basis for Conclusions of ASU 2014-09 does not preclude companies from analogizing to the guidance in ASC 606 when accounting for collaborative arrangement transactions within the scope of ASC 808. See Q&A 2-2 for considerations relevant to applying ASC 606 by analogy to collaborative arrangements.

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

ASC 808-10-20 defines a collaborative arrangement as a “contractual arrangement that involves a joint operating activity” and involves two (or more) parties that are both of the following:

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

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

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

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

- a. Directing and carrying out the activities of the joint operating activity
- b. Participating on a steering committee or other oversight or governance mechanism
- c. Holding a contractual or other legal right to the underlying intellectual property.
In addition, ASC 808-10-15-11 lists circumstances that might indicate that participants are not exposed to significant risks and rewards:

a. Services are performed in exchange for fees paid at market rates.

b. A participant is able to exit the arrangement without cause and recover all (or a significant portion) of its cumulative economic participation to date.

c. Initial profits are allocated to only one participant.

d. There is a limit on the reward that accrues to a participant.

Further, in accordance with ASC 808-10-15-12, an entity should also consider other factors when evaluating participants’ exposure to significant risks and rewards, including (1) the “stage of the endeavor’s life cycle” and (2) the “expected duration or extent of the participants’ financial participation . . . in relation to the endeavor’s total expected life or total expected value.”

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

When determining the appropriate income statement presentation of amounts recorded as a result of a collaborative arrangement, entities also will need to separately evaluate (1) transactions with third parties outside of the arrangement and (2) transactions between collaboration participants. ASC 808 requires that each collaboration participant report costs incurred and revenue generated from transactions with third parties in its income statement in accordance with the principal-versus-agent guidance in ASC 606-10-55-36 through 55-40. The participant in the collaborative arrangement that is deemed the principal participant for a given transaction should record the transaction on a gross basis in its financial statements, notwithstanding the presence of cost sharing or cost allocation of such amounts on the basis of the terms of the agreement.

In addition, participants will need to evaluate the appropriate income statement presentation for payments between the collaboration partners (e.g., as a result of expense reimbursements or profit sharing). When such payments are within the scope of other authoritative accounting literature, entities should apply the income statement classification requirements on the basis of the relevant provisions of that literature. If the payments are not within the scope of other authoritative accounting literature (e.g., ASC 606), the income statement classification for the payments is based on an analogy to authoritative accounting literature or — if there is no appropriate analogy — a reasonable, rational, and consistently applied accounting policy election.

### 2.2.1.1 Clarifying the Interaction Between ASC 808 and ASC 606

In November 2018, the FASB issued ASU 2018-18 on clarifying the interaction between ASC 808 and ASC 606. The ASU contains targeted improvements to the guidance on collaborative arrangements in ASC 808, including the following clarifications:

- In the evaluation of whether a transaction in a collaborative arrangement is within the scope of ASC 606, the unit of account is a distinct good or service.

- When the collaborative participant is a customer for a good or service (or bundle) that is distinct, the recognition, measurement, presentation, and disclosure requirements of ASC 606 should be applied to the transaction.
• An entity in a collaborative arrangement is precluded from presenting a transaction as revenue from a contract with a customer if the collaborative participant counterparty is not a customer.

While the amendments in ASU 2018-18 primarily affect the guidance in ASC 808, the ASU also amends ASC 606-10-15-3 to remove the following guidance:

A counterparty to the contract would not be a customer if, for example, the counterparty has contracted with the entity to participate in an activity or process in which the parties to the contract share in the risks and benefits that result from the activity or process (such as developing an asset in a collaboration arrangement) rather than to obtain the output of the entity's ordinary activities.

ASU 2018-18 is effective for PBEs for fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for PBEs for periods (including interim periods) for which financial statements have not yet been issued; however, an entity may not adopt ASU 2018-18 earlier than its date of adoption of ASC 606. The amendments in ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606, with a cumulative-effect adjustment recognized in the entity's opening balance of retained earnings as of the later of (1) the earliest period presented and (2) the period that includes the date of the entity's initial application of ASC 606. See Deloitte's November 13, 2018, Heads Up for more information on ASU 2018-18.

Q&A 2-2 Considerations Relevant to Applying Revenue Literature to Collaborative Arrangements by Analogy

In determining the accounting for collaborative arrangements, many entities currently apply revenue recognition guidance by analogy. These entities often conclude that the collaborative activities do not represent separate deliverables (i.e., they conclude that there is one “unit of accounting,” which represents the right to actively participate in the collaborative arrangement over its term and to share in the profits or losses from the underlying drug endeavor). Notwithstanding this conclusion, in practice the up-front proceeds that the parties exchange upon entering into the collaborative arrangement are frequently accounted for separately from the consideration subsequently exchanged as the parties fulfill their responsibilities and share costs. This accounting is often referred to as a “multiple attribution for a single unit of accounting” method of recognizing arrangement consideration in earnings.

**Question**

What considerations are relevant to entities that apply revenue literature by analogy in their determination of whether to apply the new revenue standard to collaborative arrangements?

**Answer**

ASC 606-10-25-32 states that an “entity shall apply a single method of measuring progress for each performance obligation satisfied over time, and the entity shall apply that method consistently to similar performance obligations and in similar circumstances.” This “single attribution” method differs from the multiple attribution method used in practice by many life sciences entities in accounting for their collaborative arrangements before the adoption of the new revenue standard.
Before the FASB issued ASU 2018-18, we believed that when an entity analogizes to authoritative accounting literature, all (as opposed to limited) aspects of that literature should be applied to the extent applicable. For example, a biotechnology company may enter into a collaborative arrangement with a pharmaceutical company and, as part of the collaboration, (1) provide the pharmaceutical company a license to use IP related to a drug candidate and (2) perform R&D services jointly with the pharmaceutical company. The biotechnology company may conclude that the revenue literature is applicable by analogy for determining the unit(s) of accounting, recognition, and measurement. Accordingly, if the biotechnology company concludes that the license is not a distinct performance obligation, the revenue literature would require the license and R&D services to be combined for accounting purposes. Further, with respect to the appropriate income statement presentation for consideration allocated to the combined unit of accounting (in this case, the license and R&D services), such consideration would generally be presented consistently in the same category for income statement presentation purposes given the conclusion that the license and R&D services should be combined for accounting purposes.

However, as noted above, the FASB issued ASU 2018-18 in November 2018. Although the Board decided to provide unit-of-account guidance in ASC 808 and align that guidance with the guidance in ASC 606 for distinct goods or services, the Board decided not to include recognition and measurement guidance for nonrevenue transactions in a collaborative arrangement. The Board's reason for not including such guidance was to avoid developing a “one size fits all” accounting model for the various types of collaborative arrangements. The decision to align the unit-of-account guidance with the guidance in ASC 606 for distinct goods or services is limited to the context of assessing the scope of the revenue guidance. As noted in paragraph BC31 of ASU 2018-18, “the Board decided to continue to permit an entity to apply the revenue guidance in Topic 606 by analogy or, if there is no appropriate analogy, as a policy election, without requiring the entity to apply all the guidance in Topic 606, as long as it presents the transaction separate from revenue recognized from contracts with customers” (emphasis added). Accordingly, it is possible for an entity to conclude on the basis of its facts and circumstances that ASC 606 represents an “appropriate analogy” for determining the nonrevenue unit(s) of account but may not represent an appropriate analogy for recognizing or measuring such unit(s) of account. In such a case, the above guidance would support a conclusion that analogizing to ASC 606 could be limited to an entity’s determination of the unit(s) of account. The entity would then be required to establish a policy that is “reasonable, rational, and consistently applied” as long as the nonrevenue transaction is presented separately from any revenue recognized from contracts with customers under ASC 606.

2.2.1.2 SEC Comment Letter Themes Related to Collaborative Arrangements

In the past, the SEC staff has asked registrants about the nature of, and accounting for, their collaborative arrangements and has probed to better understand the basis for such accounting under U.S. GAAP. Inquiries to registrants have focused on the registrant’s conclusion about (1) whether certain transactions with the collaboration partner represent true vendor/customer activities, (2) the registrant’s accounting policies regarding separation (i.e., unit of accounting) and allocation (i.e., when multiple units exist) for collaborative arrangements, and (3) supplemental explanation of the registrant’s determination and disclosure of (a) the separation, allocation, recognition, and classification principles that were used to account for payments between collaboration partners and (b) the factors that led the registrant to conclude that it is the principal (or agent) in transactions with third parties. The SEC staff has also requested enhanced disclosure, when material, about registrants’ collaborative arrangements, including the overall effect of collaborative arrangements on the financial statements.
We have observed that the frequency of staff comments on registrants' collaborative arrangements has decreased in recent years. However, as part of their application of the new revenue standard and ASU 2018-08, registrants need to evaluate whether transactions between partners in a collaborative arrangement are within the scope of the new revenue standard. Registrants should be mindful that the SEC staff may continue to ask them about their accounting policies for collaborative arrangements after the adoption of ASC 606 and ASU 2018-18.

2.2.2 Arrangements Involving Medical Device Consumables

The new revenue standard does not apply to contracts with customers (or portions thereof) that fall within the scope of other applicable guidance, such as ASC 840 and ASC 842 (leases). Some entities may need to obtain an understanding of the new leases standard as well as their lease contracts to determine the full scope of customer arrangements that fall within the scope of ASC 606. For example, to facilitate the sale and use of medical device consumables, medical device companies may place equipment for free at the customer's location for a multiyear term. In exchange for the placed equipment, the customer is typically required to commit to a minimum purchase of consumable products during that term.

Q&A 2-3 Considerations Relevant to Applying Revenue Literature to Free Placement of Medical Device Consumables in Exchange for the Customer's Commitment to a Minimum Purchase

Question

What considerations are relevant to the determination of how to apply the new revenue standard to this type of arrangement?

Answer

To determine how the arrangement should be accounted for under the new revenue standard, the reporting entity should first consider whether the placement of equipment meets the definition of a lease under ASC 840 (if the entity has not adopted the new leases standard) or ASC 842 (if the entity has adopted the new leases standard). If the arrangement includes elements that meet the definition of a lease, the lease-related elements of the arrangement would need to be accounted for under the lease accounting literature unless the new leases standard has been adopted and the lessor practical expedient is elected under ASC 842-10-15-42A. If the arrangement does not meet the definition of a lease and no other literature is directly applicable, the new revenue standard would be applied to the entire arrangement. For additional considerations related to the new leases standard, see Chapter 11.

2.2.3 Sale or Outlicensing of IP Rights

Life sciences entities frequently sell or outlicense IP rights (e.g., in-process R&D (IPR&D) or developed product rights) in exchange for future milestone payments, royalties, or both (i.e., variable consideration).
Q&A 2-4 Determining the Accounting Model to Apply to the Sale or Outlicensing of IP Rights in Exchange for Future Milestone Payments, Royalties, or Both

**Question**
What considerations are relevant to the determination of the accounting model to apply to these types of arrangement?

**Answer**
Transactions involving the transfer of IP rights require significant judgment. Accounting for these transactions depends on whether the transfer involves (1) the sale of IP rights, (2) the license of IP rights, or (3) the sale of IP rights together with other inputs and processes that meet the definition of a business:

- **Sale of IP rights** — The new revenue standard's provisions apply to transfers of nonfinancial assets, including in-substance nonfinancial assets that are not an output of an entity's ordinary activities (e.g., intangible assets such as IP rights). The following example in ASC 610-20-55-17 through 55-19 illustrates how an entity would account for the sale of a nonfinancial asset in exchange for variable consideration:

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ASC 610-20

Example 3 — Sale of a Nonfinancial Asset for Variable Consideration

55-17 An entity sells (that is, does not out license) the rights to in-process research and development that it recently acquired in a business combination and measured at fair value of $50 million in accordance with Topic 805 on business combinations. The entity concludes that the transferred in-process research and development is not a business. The buyer of the in-process research and development agrees to pay a nonrefundable amount of $5 million at inception plus 2 percent of sales of any products derived from the in-process research and development over the next 20 years. The entity concludes that the sale of in-process research and development is not a good or service that is an output of the entity's ordinary activities.
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Chapter 2 — Revenue Recognition

ASC 610-20 (continued)

55-18 Topic 350 on goodwill and other intangibles requires the entity to apply the guidance in this Subtopic to determine the amount and timing of income to be recognized. Therefore, the entity applies the derecognition guidance in this Subtopic as follows:

a. The entity concludes that it does not have a controlling financial interest in the buyer.

b. The entity concludes that the contract meets the criteria in paragraph 606-10-25-1.

c. The entity also concludes that on the basis of the guidance in paragraph 606-10-25-30, it has transferred control of the in-process research and development asset to the buyer. This is because the buyer can use the in-process research and development’s records, patents, and supporting documentation to develop potential products and the entity has relinquished all substantive rights to the in-process research and development asset.

d. In estimating the consideration received, the entity applies the guidance in Topic 606 on determining the transaction price, including estimating and constraining variable consideration. The entity estimates that the amount of consideration that it will receive from the sales-based royalty is $100 million over the 20-year royalty period. However, the entity cannot assert that it is probable that recognizing all of the estimated variable consideration in other income would not result in a significant reversal of that consideration. The entity reaches this conclusion on the basis of its assessment of factors in paragraph 606-10-32-12. In particular, the entity is aware that the variable consideration is highly susceptible to the actions and judgments of third parties, because it is based on the buyer completing the in-process research and development asset, obtaining regulatory approval for the output of the in-process research and development asset, and marketing and selling the output. For the same reasons, the entity also concludes that it could not include any amount, even a minimum amount, in the estimate of the consideration. Consequently, the entity concludes that the estimate of the consideration to be used in the calculation of the gain or loss upon the derecognition of the in-process research and development asset is limited to the $5 million fixed upfront payment.

55-19 At inception of the contract, the entity recognizes a net loss of $45 million ($5 million of consideration, less the in-process research and development asset of $50 million). The entity reassesses the transaction price at each reporting period to determine whether it is probable that a significant reversal would not occur from recognizing the estimate as other income and, if so, recognizes that amount as other income in accordance with paragraphs 606-10-32-14 and 606-10-32-42 through 32-45.

- **License of IP rights** — In contrast to the accounting for a sale of IP, for a licensing transaction in which consideration is tied to the subsequent sale or usage of IP, the new revenue standard provides an exception to the recognition principle that is part of step 5 (i.e., recognize revenue when or as control of the goods or services is transferred to the customer). Under this sales- or usage-based royalty exception, an entity would not estimate the variable consideration from sales- or usage-based royalties. Instead, the entity would recognize revenue at the later of when (1) the subsequent sale or usage occurs or (2) the performance obligation to which some or all of the sales- or usage-based royalty has been allocated is satisfied (or partially satisfied).

- **Sale of IP rights together with other inputs and processes that meet the definition of a business** — ASC 610-20 does not amend or supersede guidance that addresses how to determine the gain or loss on the derecognition of a subsidiary or a group of assets that meets the definition of a business. Gains or losses associated with such a transaction will continue to be determined in accordance with ASC 810-10-40. As discussed in Q&A 4-12, entities should establish an accounting policy for the initial and subsequent measurement of this type of arrangement.
2.3 Identify the Contract (Step 1)

For contracts within the scope of ASC 606, the first step of the new revenue standard is to determine whether a contract exists, for accounting purposes, between an entity and its customer.

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<th>ASC 606-10</th>
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<tbody>
<tr>
<td><strong>25-1</strong> An entity shall account for a contract with a customer that is within the scope of this Topic only when all of the following criteria are met:</td>
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<tr>
<td>a. The parties to the contract have approved the contract (in writing, orally, or in accordance with other customary business practices) and are committed to perform their respective obligations.</td>
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<tr>
<td>b. The entity can identify each party's rights regarding the goods or services to be transferred.</td>
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<tr>
<td>c. The entity can identify the payment terms for the goods or services to be transferred.</td>
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<tr>
<td>d. The contract has commercial substance (that is, the risk, timing, or amount of the entity's future cash flows is expected to change as a result of the contract).</td>
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<td>e. It is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer (see paragraphs 606-10-55-3A through 55-3C). In evaluating whether collectibility of an amount of consideration is probable, an entity shall consider only the customer's ability and intention to pay that amount of consideration when it is due. The amount of consideration to which the entity will be entitled may be less than the price stated in the contract if the consideration is variable because the entity may offer the customer a price concession (see paragraph 606-10-32-7).</td>
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A contract does not have to be written to meet the criteria for revenue recognition. However, it does need to create enforceable rights and obligations.

Some of the more common questions that life sciences entities have faced when considering step 1 of the new revenue standard are discussed below.

Q&A 2-5 Identifying the Parties That Are Relevant to the Determination of Whether a Contract Exists

*Question*

Given the number of entities involved in the distribution channel or pricing chain within the life sciences industry, questions have arisen about which parties are relevant to the determination of whether a contract exists. For example, for a pharmaceutical company, does a contract for purposes of step 1 include only the contract between the pharmaceutical company and the wholesaler, or does it also include "downstream" contracts with others in the pricing chain to whom discounts or rebates may be provided?
Chapter 2 — Revenue Recognition

Answer
An important step in the new revenue standard is determining when an agreement with a customer represents a contract for accounting purposes. The criteria in ASC 606-10-25-1 that need to be in place to establish that a contract exists are intended to demonstrate that there is a valid and genuine transaction between an entity and its customer and that the parties to the contract have enforceable rights and obligations that will have true economic consequences. For a traditional pharmaceutical company, the wholesaler to which the company’s products are shipped would generally represent the customer. In these circumstances, other parties that may be involved in the distribution channel or pricing chain do not represent the company’s customers and therefore are irrelevant to the determination of whether a contract exists for accounting purposes. However, life sciences entities should keep in mind that any pricing adjustments (e.g., rebates, chargebacks) that are payable as result of this type of arrangement may represent variable consideration that is required to be estimated and potentially constrained under step 3 of the model.

Q&A 2-6  Whether the Transaction Price Must Be Fixed or Determinable

Question
Does the criterion in ASC 606-10-25-1 that the “entity can identify the payment terms for the goods or services to be transferred” (emphasis added) require that the transaction price be fixed or determinable as required under legacy guidance?

Answer
No. A contract must include payment terms for each of the promised goods and services in an arrangement for an entity to determine the transaction price. The payment terms do not need to be fixed, but the contract must contain enough information to allow an entity to reasonably estimate the consideration to which it will be entitled for transferring the goods and services to the customer.

Example
Pharmaceutical Company X has received approval from a foreign government to sell drug A to government hospitals in advance of obtaining full market authorization in the jurisdiction. During this “early access period” in which X’s application for full marketing authorization is being evaluated by the foreign government, X will be paid a preliminary price by the government hospitals. During this same period, X will be negotiating with the foreign government the final price to be paid to X. Upon obtaining full marketing authorization and completing pricing negotiations, X will be required to rebate to the foreign government the difference between the preliminary price and the final price.

Under legacy guidance, the lack of a fixed or determinable final selling price would generally preclude the recognition of revenue until the final price is determined. Under the new revenue standard, however, payment terms may have been established between X and the government hospitals because X can (1) determine, for example, when payment is due and that the consideration is variable and (2) reasonably estimate the amount of consideration to which it will ultimately be entitled on the basis of the ongoing negotiations with the foreign government.
Q&A 2-7  Price Concessions

Question
How do price concessions (variable consideration) affect the assessment of a contract under ASC 606-10-25-1(e), which requires that “[i]t is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer” (emphasis added)?

Answer
As part of determining whether a valid and genuine contract exists, an entity is required to evaluate whether it is probable that the entity will collect substantially all of the consideration to which it is entitled under the contract. However, the consideration to which an entity is ultimately entitled may be less than the price stated in the contract because the customer is offered a price concession. Price concessions are a form of variable consideration and need to be analyzed when the transaction price is being determined (as part of step 3 of the new revenue model). However, as part of step 1, an entity would evaluate whether it is probable that the entity will collect the consideration to which it will be entitled for providing goods or services to a customer after considering any price concessions. This evaluation requires aspects of step 3 to be performed in conjunction with step 1. Differentiating between credit risk (i.e., the risk of collecting less consideration than the amount the entity legitimately expected to collect from the customer) and price concessions (i.e., entering into a contract with a customer with the expectation of accepting less than the contractual amount of consideration in exchange for goods or services) may be difficult. Entities will need to use significant judgment in determining whether they have provided an implicit price concession or have accepted a customer’s credit risk. This is particularly true of entities in highly regulated industries, such as health care and consumer energy, which may be required by law to provide certain goods and services to their customers regardless of the customers’ ability to pay. Because of the nature of these arrangements, entities will need to evaluate all of the relevant facts and circumstances of their arrangements to determine whether they have provided implicit price concessions or whether the anticipated receipt of less than the total contractual consideration represents credit risk.

Example 2 in ASC 606-10-55-99 through 55-101, which is reproduced below, illustrates how a life sciences entity would evaluate implicit price concessions when assessing whether the collectibility criterion is met.

ASC 606-10

Example 2 — Consideration Is Not the Stated Price — Implicit Price Concession

55-99 An entity sells 1,000 units of a prescription drug to a customer for promised consideration of $1 million. This is the entity’s first sale to a customer in a new region, which is experiencing significant economic difficulty. Thus, the entity expects that it will not be able to collect from the customer the full amount of the promised consideration. Despite the possibility of not collecting the full amount, the entity expects the region’s economy to recover over the next two to three years and determines that a relationship with the customer could help it to forge relationships with other potential customers in the region.
Chapter 2 — Revenue Recognition

ASC 606-10 (continued)

55-100 When assessing whether the criterion in paragraph 606-10-25-1(e) is met, the entity also considers paragraphs 606-10-32-2 and 606-10-32-7(b). Based on the assessment of the facts and circumstances, the entity determines that it expects to provide a price concession and accept a lower amount of consideration from the customer. Accordingly, the entity concludes that the transaction price is not $1 million and, therefore, the promised consideration is variable. The entity estimates the variable consideration and determines that it expects to be entitled to $400,000.

55-101 The entity considers the customer’s ability and intention to pay the consideration and concludes that even though the region is experiencing economic difficulty it is probable that it will collect $400,000 from the customer. Consequently, the entity concludes that the criterion in paragraph 606-10-25-1(e) is met based on an estimate of variable consideration of $400,000. In addition, based on an evaluation of the contract terms and other facts and circumstances, the entity concludes that the other criteria in paragraph 606-10-25-1 are also met. Consequently, the entity accounts for the contract with the customer in accordance with the guidance in this Topic.

2.3.1 Contract Term

Determining the term of the contract is an important step in the revenue recognition process since the contract term could affect the identification of promises under the contract, the transaction price, and disclosures. ASC 606 provides guidance on determining the contract duration, including the effect of termination clauses and contract renewals. The contract term is determined on the basis of the period over which the parties to the contract have present enforceable rights and obligations.

ASC 606-10

25-3 Some contracts with customers may have no fixed duration and can be terminated or modified by either party at any time. Other contracts may automatically renew on a periodic basis that is specified in the contract. An entity shall apply the guidance in this Topic to the duration of the contract (that is, the contractual period) in which the parties to the contract have present enforceable rights and obligations. In evaluating the criterion in paragraph 606-10-25-1(e), an entity shall assess the collectibility of the consideration promised in a contract for the goods or services that will be transferred to the customer rather than assessing the collectibility of the consideration promised in the contract for all of the promised goods or services (see paragraphs 606-10-55-3A through 55-3C). However, if an entity determines that all of the criteria in paragraph 606-10-25-1 are met, the remainder of the guidance in this Topic shall be applied to all of the promised goods or services in the contract.

In the life sciences industry, contract research organizations (CROs) typically enter into long-term contracts with their customers to perform clinical trial management services. Because of the high failure rates in the clinical development process, it is customary for CROs in the industry to provide the customer the right to terminate the contract with the CRO without cause. The customer is often required to give a specified notice of termination (e.g., 30 days) and to compensate the CRO for all work performed through the date of termination, as well as for any noncancelable arrangements the CRO has entered into and any wind-down activities required to close the study. In addition, some contracts may include a termination fee for early cancellation of a study.
Q&A 2-8  Considerations for Evaluating the Impact of Termination Provisions on the Determination of the Contract Term

**Question**
What factors should an entity (e.g., a CRO) consider when evaluating the impact of termination provisions on the determination of the contract term?

**Answer**
The TRG noted that the duration of a contract is predicated on the contract’s enforceable rights and obligations. Accordingly, regardless of whether one or both parties have the right to terminate the contract, an entity would need to evaluate the nature of the termination provisions, including whether they are substantive. For example, an entity would assess factors such as (1) whether the terminating party is required to pay compensation, (2) the amount of such compensation, and (3) the reason for the compensation (i.e., whether the compensation is in addition to amounts due for goods and services already delivered). Substantive termination penalties suggest that the parties’ rights and obligations extend for the duration of the contract term.

TRG members acknowledged that the determination of whether a termination provision is substantive will require judgment and would be evaluated both quantitatively and qualitatively. Some offered that data about the frequency of contract terminations may be useful in such a determination (i.e., a high frequency of payments made to terminate contracts may suggest that the termination provision is not substantive).

Further, TRG members generally agreed that a contract’s accounting term could be less than the contract’s stated term if termination provisions are not substantive. That is, a 12-month stated contract term could, in effect, be a month-to-month contract if the contract could be terminated with one month’s notice and the termination penalties are not substantive. An entity will need to carefully consider the effect of nonsubstantive termination provisions and clauses on the timing and amount of revenue to be recognized.

In practice, CROs often experience a low frequency of payments made to terminate contracts, which may suggest that the termination provisions are substantive. A substantive termination penalty is evidence of enforceable rights and obligations on the part of both parties throughout the period in which the substantive termination penalty applies.

Q&A 2-9  Determining Whether a License Arrangement Includes a Substantive Termination Penalty

Company A, a pharmaceutical company in the United States, owns and maintains a portfolio of patents related to an antibiotic that treats life-threatening diseases. On February 23, 20X8, A grants Customer B (a pharmaceutical company in Ireland) the exclusive right to use its patented drug formula to commercialize and supply the antibiotic in Europe. The IP is fully developed, and regulatory approval has been obtained; therefore, B is able to commercialize the IP. Company A has determined that the patented drug formula is functional IP and that therefore, the license grants B the right to use the IP.
In exchange for the exclusive right to use the patented drug formula, B agrees to pay A the following amounts:

- An up-front fee of $300 million.
- Annual fixed fees of $50 million payable at the end of each year in which the contract is effective.
- Sales-based royalties of 5 percent of B's sales of the antibiotic in Europe (recognized in accordance with the sales-based royalty exception in ASC 606-10-55-65).

The contract states that B has the exclusive right to use the patented drug formula through the patent term, which expires in 10 years (i.e., the contract ends when the patent expires). Notwithstanding the stated contract term, the contract states that B may terminate the contract before the expiration of the patent by providing three months' notice to A. All amounts already paid by B are nonrefundable in the event of early termination. The contract does not include an explicit termination penalty (i.e., B is not required to pay additional cash consideration to A upon early termination); however, upon early termination, the right to the patented drug formula in Europe would revert back to A, and A would be able to relicense the patented drug formula to a different pharmaceutical company in Europe. Unless B terminates the contract before the end of the stated term, A would not be able to benefit from licensing the patented drug formula to a different pharmaceutical company in Europe (i.e., A would receive this benefit only upon B's early termination of the contract).

**Question**

Does A's contract to license the exclusive right to use its patented drug formula to B contain a substantive termination penalty?

**Answer**

Yes. It is important for an entity to evaluate the nature of the termination provisions in its contracts to determine the appropriate contract term for applying ASC 606. When determining whether a termination penalty is substantive, an entity should consider factors such as:

- Whether the terminating party is required to pay compensation.
- The amount of such compensation.
- The reason for the compensation (i.e., whether the compensation is in addition to amounts due for goods and services already delivered).

In the fact pattern above, A's contract to license the patented drug formula to B does not include an explicit termination penalty. That is, B can terminate the contract before the end of the stated term by providing three months' notice without paying additional cash consideration to A. Although the contract does not require B to pay additional cash consideration to A upon early termination, in the event that B terminates the contract early, the exclusive license rights related to the patented drug formula would revert back to A. Company A would then be able to license the patented drug formula to another customer in Europe for the remainder of the patent term, which it would not have been able to do if B had not terminated the contract. Therefore, although B is not paying additional cash to A upon termination, B is providing consideration (i.e., something of value) to A, and A is receiving something of value from B (i.e., the right to relicense the patented drug formula), upon termination. Although the TRG's discussion focused
on compensation as additional cash that an entity’s customer would pay to the entity upon termination, compensation may also include noncash consideration that is of value to the entity. The fact that B is forfeiting its rights to the patented drug formula and providing A with something of value (i.e., the ability to relicense the patented drug formula to another customer in Europe) from the forfeiture upon early termination represents a substantive termination penalty in the contract.

The substantive termination penalty suggests that the parties’ rights and obligations extend for the duration of the stated contract term. That is, the contract term is 10 years.

### 2.3.2 Contract Modifications

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<tr>
<td><strong>25-10</strong> A contract modification is a change in the scope or price (or both) of a contract that is approved by the parties to the contract. In some industries and jurisdictions, a contract modification may be described as a change order, a variation, or an amendment. A contract modification exists when the parties to a contract approve a modification that either creates new or changes existing enforceable rights and obligations of the parties to the contract. A contract modification could be approved in writing, by oral agreement, or implied by customary business practices. If the parties to the contract have not approved a contract modification, an entity shall continue to apply the guidance in this Topic to the existing contract until the contract modification is approved.</td>
</tr>
<tr>
<td><strong>25-11</strong> A contract modification may exist even though the parties to the contract have a dispute about the scope or price (or both) of the modification or the parties have approved a change in the scope of the contract but have not yet determined the corresponding change in price. In determining whether the rights and obligations that are created or changed by a modification are enforceable, an entity shall consider all relevant facts and circumstances including the terms of the contract and other evidence. If the parties to a contract have approved a change in the scope of the contract but have not yet determined the corresponding change in price, an entity shall estimate the change to the transaction price arising from the modification in accordance with paragraphs 606-10-32-5 through 32-9 on estimating variable consideration and paragraphs 606-10-32-11 through 32-13 on constraining estimates of variable consideration.</td>
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Contract modifications can frequently happen in the normal course of business. Any time an entity and its customer agree to change what the entity promises to deliver or the amount of consideration the customer will pay, there is a contract modification. Therefore, the first step in the identification of a contract modification is to assess whether, for a contract accounted for under ASC 606, there has been a change in the contract’s scope or price, or both. The second step is to determine whether the parties to the contract have agreed upon the change. As noted above, contract modifications must be agreed to by both parties (written, orally, or through customary business practices). That is, both parties must agree to change the enforceable rights and obligations of the contract.

As noted above, CROs in the life sciences industry often enter into long-term contracts with their customers to perform clinical trial management services. Changes in the scope of these contracts is common in the industry.
If a CRO and its customer agree upon a change to a contract and the change qualifies as a contract modification under ASC 606-10-25-10 and 25-11, the CRO will be required to evaluate the appropriate accounting for that contract modification.

Q&A 2-10 Considerations for Determining How to Account for a Modification Involving a Change in the Contract’s Scope or Price

Question
When a change in a contract’s scope, price, or both occurs, what factors should an entity (e.g., a CRO) consider in determining how to account for that modification?

Answer
The entity must assess the goods and services and their selling price. Depending on whether those goods and services are distinct or sold at the stand-alone selling price, a modification can be accounted for as:

- A separate contract (see ASC 606-10-25-12).
- One of the following (if the modification is not accounted for as a separate contract):
  - A termination of the old contract and the creation of a new contract (see ASC 606-10-25-13(a)).
  - A cumulative catch-up adjustment to the original contract (see ASC 606-10-25-13(b)).
  - A combination of the items described in ASC 606-10-25-13(a) and (b), in a way that faithfully reflects the economics of the transaction (see ASC 606-10-25-13(c)).

2.3.2.1 Contract Modification Accounted for as a Separate Contract

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<th>ASC 606-10</th>
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<tr>
<td><strong>25-12</strong> An entity shall account for a contract modification as a separate contract if both of the following conditions are present:</td>
</tr>
<tr>
<td>a. The scope of the contract increases because of the addition of promised goods or services that are distinct (in accordance with paragraphs 606-10-25-18 through 25-22).</td>
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<tr>
<td>b. The price of the contract increases by an amount of consideration that reflects the entity’s standalone selling prices of the additional promised goods or services and any appropriate adjustments to that price to reflect the circumstances of the particular contract. For example, an entity may adjust the standalone selling price of an additional good or service for a discount that the customer receives, because it is not necessary for the entity to incur the selling-related costs that it would incur when selling a similar good or service to a new customer.</td>
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With the overall goal of accurately representing the economics of the transaction in mind, the FASB and IASB decided that there is no economic difference between (1) the modification of an existing contract with a customer to include additional distinct goods or services at their representative stand-alone selling price and (2) a completely new contract entered into by the two parties. Therefore, a contract modification should be accounted for as a separate contract only if there are additional distinct goods or services promised to a customer as a result of the modification. However, for the contract modification to be accounted for as a separate contract, those goods or services must be in exchange for consideration that represents the stand-alone selling price of the additional distinct promised goods or services.

Because a modification to a CRO contract often may not add “distinct” goods or services at a price that reflects the stand-alone selling price of those goods or services, such a modification is generally not accounted for as a new contract separate from the original contract. Instead, as further discussed below, this type of modification is typically (1) viewed as part of a single performance obligation that is partially satisfied on the date of the modification and (2) accounted for as if it were part of the original contract.

A modification that results in a decrease in scope cannot be accounted for as a separate contract because the criterion in ASC 606-10-25-12(a) specifying an increase in the scope of the contract is not met.

### 2.3.2.2 Contract Modification Not Accounted for as a Separate Contract

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<td><strong>25-13</strong></td>
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<td>a.</td>
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<td>c.</td>
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If a contract modification does not meet the requirements to be accounted for as a separate contract, an entity would have to determine how to account for a blended contract that now includes one or both of the following:

- An original agreement plus or minus some other goods or services.
- A change in the amount of consideration due under the modified arrangement.

The determination of which model to use depends on whether the remaining goods or services (the originally promised items and the newly promised items) are distinct from the goods and services already provided under the contract.

If the remaining goods or services are distinct from those already provided under the original arrangement, the entity would in effect establish a “new” contract that includes only those remaining goods and services. In this situation, the entity would allocate to the remaining performance obligations in the contract (1) consideration from the original contract that has not yet been recognized as revenue and (2) any additional consideration from the modification.

In contrast, if the contract modification results in remaining goods and services that are not distinct, the entity should account for the modification as though the additional goods and services were an addition to an incomplete performance obligation. This may be the case when a CRO’s contract with a customer contains one performance obligation and the parties modify the terms to change the scope of the services provided. In this instance, a measure of progress, such as costs incurred, would typically be used to recognize the revenue. For example, suppose that just before the modification, the entity’s performance was 30 percent complete. After the modification, the entity may determine that its performance is only 25 percent complete (or 35 percent complete). As a result, an updated revenue figure is calculated on the basis of the revised percentage, and the entity would record a cumulative catch-up adjustment.

The FASB and IASB recognized that there may be contracts in which some performance obligations include remaining goods or services that are distinct from those already provided under the original arrangement, while other performance obligations include remaining goods and services that are not (i.e., a change in scope of a partially satisfied performance obligation). In those circumstances, the boards decided that it may be appropriate, as described in ASC 606-10-25-13(c), to apply each of the models to parts of a contract. An entity would do so by accounting for the performance obligations that are not yet fully satisfied (i.e., including those that are partially satisfied). No change would be made to revenue recognized for fully satisfied performance obligations.

### 2.4 Identify the Performance Obligations (Step 2)

Step 2 is one of the most critical steps in the new revenue framework since it establishes the unit of account for revenue recognition. This step requires an entity to identify what it has promised to the customer. The entity then determines whether a promise or multiple promises represent one or more performance obligations to the customer. To accomplish this, the entity should determine whether the promises in the contract are distinct. ASC 606-10-25-19 notes that a “good or service that is promised to a customer is distinct if both of the following criteria are met”:

a. The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct).

b. The entity’s promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract).
Further, ASC 606-10-25-22 states that “[i]f a promised good or service is not distinct, an entity shall combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. In some cases, that would result in the entity accounting for all the goods or services promised in a contract as a single performance obligation.”

The new revenue standard’s guidance on determining whether a customer can benefit from a good or service on its own or together with other readily available resources is generally consistent with the legacy guidance in ASC 605-25 on determining whether a good or service has stand-alone value. However, the requirement that a good or service be “separately identifiable from other promises in the contract” is a new concept under which entities must further evaluate a good or service for separability.

To help an entity assess whether its promises to transfer goods or services to the customer are separately identifiable, ASC 606-10-25-21 identifies the following factors “that indicate that two or more promises to transfer goods or services to a customer are not separately identifiable” (emphasis added):

a. The entity provides a significant service of integrating [the] goods or services with other goods or services promised in the contract into a bundle of goods or services that represent the combined output or outputs for which the customer has contracted. . . .

b. One or more of the goods or services significantly modifies or customizes, or are significantly modified or customized by, one or more of the other goods or services promised in the contract.

c. The goods or services are highly interdependent or highly interrelated. In other words, each of the goods or services is significantly affected by one or more of the other goods or services in the contract. For example, in some cases, two or more goods or services are significantly affected by each other because the entity would not be able to fulfill its promise by transferring each of the goods or services independently.

In the life sciences industry, CROs often provide multiple services for their pharmaceutical and biotechnology customers. For example, CROs may help design studies, recruit investigators (physicians), recruit patients, help manage clinical trials, monitor safety, and write reports on study results. These services are generally considered to represent a single performance obligation because they are not “separately identifiable.”

Some of the more common questions that life sciences entities have faced when considering step 2 of the new revenue standard are discussed below.

**Q&A 2-11 License of IP Bundled With Other Services**

Arrangements involving the license of IP and other services (e.g., contract R&D services or contract manufacturing services) are common in the life sciences industry. For example, biotechnology companies frequently enter into license and development arrangements with pharmaceutical companies, and contract manufacturers frequently enter into license and supply arrangements with pharmaceutical companies.

**Question**

With respect to identifying performance obligations, how does the analysis of such arrangements under ASC 606 compare with that under legacy guidance?
Answer
Life sciences entities that grant a license bundled with other services (e.g., contract R&D services or contract manufacturing services) may need to use significant judgment when determining whether the goods or services in a contract (1) are capable of being distinct (have stand-alone value) and (2) are not highly interdependent or highly interrelated and do not significantly modify or customize one another (are separately identifiable). While the analysis of whether the goods or services are capable of being distinct is generally consistent with the analysis of “standalone value” under legacy guidance, the “separately identifiable” concept is new and may require entities to account for a bundle of goods or services, which may represent separate units of accounting under legacy guidance, as a single performance obligation (unit of accounting).

Q&A 2-12 Considering Whether It Is Feasible for Another Vendor to Perform the Same Services

Question
In the evaluation of whether a license of IP and contract R&D services (or contract manufacturing services) are separate performance obligations, how should an entity consider whether it is feasible for another vendor to provide the same services?

Answer
ASC 606-10-55-367 through 55-372A, relevant parts of which are reproduced below, include two fact patterns that illustrate how the determination of whether it is feasible for another life sciences entity to provide the same services affects the analysis of whether the “capable of being distinct” criterion is met.

ASC 606-10

Example 56 — Identifying a Distinct License

55-367 An entity, a pharmaceutical company, licenses to a customer its patent rights to an approved drug compound for 10 years and also promises to manufacture the drug for the customer for 5 years, while the customer develops its own manufacturing capability. The drug is a mature product; therefore, there is no expectation that the entity will undertake activities to change the drug (for example, to alter its chemical composition). There are no other promised goods or services in the contract.

Case A — License Is Not Distinct

55-368 In this case, no other entity can manufacture this drug while the customer learns the manufacturing process and builds its own manufacturing capability because of the highly specialized nature of the manufacturing process. As a result, the license cannot be purchased separately from the manufacturing service.

55-369 The entity assesses the goods and services promised to the customer to determine which goods and services are distinct in accordance with paragraph 606-10-25-19. The entity determines that the customer cannot benefit from the license without the manufacturing service; therefore, the criterion in paragraph 606-10-25-19(a) is not met. Consequently, the license and the manufacturing service are not distinct, and the entity accounts for the license and the manufacturing service as a single performance obligation.
ASC 606-10 (continued)

Case B — License Is Distinct

55-371 In this case, the manufacturing process used to produce the drug is not unique or specialized, and several other entities also can manufacture the drug for the customer.

55-372 The entity assesses the goods and services promised to the customer to determine which goods and services are distinct, and it concludes that the criteria in paragraph 606-10-25-19 are met for each of the license and the manufacturing service. The entity concludes that the criterion in paragraph 606-10-25-19(a) is met because the customer can benefit from the license together with readily available resources other than the entity’s manufacturing service (that is, because there are other entities that can provide the manufacturing service) and can benefit from the manufacturing service together with the license transferred to the customer at the start of the contract.

55-372A The entity also concludes that its promises to grant the license and to provide the manufacturing service are separately identifiable (that is, the criterion in paragraph 606-10-25-19(b) is met). The entity concludes that the license and the manufacturing service are not inputs to a combined item in this contract on the basis of the principle and the factors in paragraph 606-10-25-21. In reaching this conclusion, the entity considers that the customer could separately purchase the license without significantly affecting its ability to benefit from the license. Neither the license nor the manufacturing service is significantly modified or customized by the other, and the entity is not providing a significant service of integrating those items into a combined output. The entity further considers that the license and the manufacturing service are not highly interdependent or highly interrelated because the entity would be able to fulfill its promise to transfer the license independent of fulfilling its promise to subsequently manufacture the drug for the customer. Similarly, the entity would be able to manufacture the drug for the customer even if the customer had previously obtained the license and initially utilized a different manufacturer. Thus, although the manufacturing service necessarily depends on the license in this contract (that is, the entity would not contract for the manufacturing service without the customer having obtained the license), the license and the manufacturing service do not significantly affect each other. Consequently, the entity concludes that its promises to grant the license and to provide the manufacturing service are distinct and that there are two performance obligations:

a. License of patent rights
b. Manufacturing service.

Connecting the Dots

Determining whether R&D services or manufacturing services are separately identifiable from licenses can require significant judgment. While “bright lines” do not exist, the stage of development may be relevant to the determination of whether R&D services are expected to significantly modify or customize the IP (e.g., R&D services for early-stage IP frequently involve activities that lead to changes in a drug compound’s formulation, dosing levels, and manufacturing process, whereas R&D services for later-stage IP may only involve validating the drug’s efficacy).

Similarly, if the manufacturing of active pharmaceutical ingredient (API) is performed to support R&D services, the manufacturing and R&D may not be distinct because the company cannot fulfill its promise to perform R&D independently from its promise to manufacture API. Conversely, manufacturing of an approved product may be more likely to be “distinct” if another party could perform the services.
Q&A 2-13  Contractual Requirement That the Entity’s Customer Must Use the Entity’s Services

Question
In the evaluation of whether a license of IP and contract R&D services (or contract manufacturing services) are separate performance obligations, how should an entity consider a contractual requirement that the entity’s customer must use the entity’s services?

Answer
A contractual requirement that the entity’s customer must use the entity’s R&D services (or manufacturing services) does not change the evaluation of whether the promised goods and services are distinct. In accordance with ASC 606-10-55-150F, “[t]his is because the contractual requirement to use the entity’s . . . services does not change the characteristics of the goods or services themselves, nor does it change the entity’s promises to the customer.” Specifically, paragraph BC100 of ASU 2014-09 notes the following:

The Boards observed that the assessment of whether the “customer can benefit from the goods or services on its own” should be based on the characteristics of the goods or services themselves instead of the way in which the customer may use the goods or services. Consequently, an entity would disregard any contractual limitations that might preclude the customer from obtaining readily available resources from a source other than the entity.

Accordingly, if the license and the services are otherwise capable of being distinct and separately identifiable, the license and the services would be accounted for as two performance obligations.

Q&A 2-14  Determining Whether Other Promises in the Life Sciences Industry Are Separate Performance Obligations

The illustrative examples in ASC 606 provide certain facts used to support a determination of whether a promised good or service is distinct and therefore a separate performance obligation. However, some facts may vary between examples while the conclusions are consistent. For instance, in Example 11, Case C (ASC 606-10-55-150A through 55-150D), one of the facts provided to support the conclusion that the equipment and installation services represent two performance obligations is that others can provide the installation services. However, in Example 11, Case E (ASC 606-10-55-150G through 55-150K), one of the facts provided to support the conclusion that the equipment and specialized consumables are also two performance obligations is that the specialized consumables are not available from other entities.

Question
If a good or service (e.g., installation service) is unavailable from alternative providers or available from only a limited number of alternative providers, is an entity precluded from considering the good or service to be a separate performance obligation?
Answer

No. The unavailability of a good or service from alternative providers is a factor for an entity to consider in evaluating whether the good or service is distinct (and therefore a separate performance obligation), but that factor is not individually determinative (as noted in the examples cited above). Entities need to use judgment in evaluating whether a promise to provide a good or service, in addition to other goods or services, is capable of being distinct and is distinct within the context of the contract (i.e., separately identifiable) in accordance with ASC 606-10-25-19. In making that determination, an entity may focus on why a good or service is or is not available from other providers, especially when evaluating the following factors in ASC 606-10-25-21 to conclude on whether the good or service is separately identifiable:

- Whether there is a significant service of integrating goods or services.
- Whether the good or service significantly modifies or customizes another good or service.
- Whether the good or service is highly dependent on or highly interrelated with any other goods or services.

For example, if an entity sells medical device equipment and provides installation of that equipment, the determination of whether the installation services are available from another entity would be a factor to be considered in the evaluation of whether the installation is distinct within the context of the contract, but that factor alone would not be determinative. It is important for the reporting entity to consider why the installation is unavailable from (or available from only a limited number of) alternative providers to determine whether the installation is separately identifiable in accordance with ASC 606-10-25-21. For example, if the entity has a standard installation process that does not significantly customize or modify the equipment for the entity’s customer, the entity may conclude that the installation is separately identifiable regardless of whether there are no other installation providers or only a limited number of such providers. However, installation services that are unique and significantly modify or customize the equipment for the customer may suggest that the services are not separately identifiable and therefore are not distinct within the context of the contract.

Connecting the Dots

In the life sciences industry, manufacturing facilities and processes are frequently required to be approved by regulators (e.g., the FDA). The absence of alternative facilities with regulatory approval to manufacture a particular product can affect the “distinct” analysis for arrangements involving a license of IP and manufacturing services.

Similarly, biotechnology companies that enter into revenue arrangements with pharmaceutical companies are frequently required by contract to participate in a joint steering committee in addition to licensing a drug candidate and performing R&D services. Although the obligation to participate in a joint steering committee could be determined to be a promised service, it may not represent a “distinct” service unless, for example, other parties could perform the service and the service does not involve a significant integration of other goods and services in the arrangement.
Q&A 2-15 Application of the Series Provision in Life Sciences Arrangements

Entities in the life sciences industry may enter into service arrangements with other entities in the industry as part of their product development process or commercialization strategies. For example, the developer of a drug compound or other IP may enter into an arrangement with a CRO for clinical research services (“R&D services”). These R&D services may involve various tasks such as patient enrollment, clinical trial site management, and activities related to regulatory filings. While the two entities agree to a set of objectives, the CRO providing the R&D services may not promise or guarantee an end result. Instead, the CRO satisfies its performance obligation to the IP developer by giving the developer access to clinical professionals to advance the R&D efforts toward agreed-upon objectives. Given the nature of such R&D services, the services may not be performed consistently or consecutively over the service period, and their nature and scope may change as the work progresses.

Conversely, a life sciences entity may commercialize its approved pharmaceutical products by retaining an outsourced sales team to promote and sell its products. The nature of the selling services may differ from R&D services in that each day's service is not modified or customized by another day's service, one day's service is not an input with another day's service that results in a combined output, and each day's service is not highly interdependent or interrelated with another day's service.

An entity's application of ASC 606 to a contract with a customer may be affected by whether the entity determines that its promises to the customer represent (1) a single combined performance obligation comprising multiple activities that are not distinct or (2) a single performance obligation consisting of a series of distinct increments. Specifically, the application of the guidance on allocating variable consideration, accounting for contract modifications, and providing disclosures related to remaining performance obligations differs for a series of distinct increments of goods or services. The determination of whether R&D or selling services provided by entities in the life sciences industry represent a series may require significant judgment.

Question

Do R&D or selling services in the life sciences industry meet the criteria in ASC 606-10-25-15 to be accounted for as a series?

Answer

It depends. The first step in the evaluation of whether an entity’s promise to provide R&D or selling services to a customer represents a series is to assess whether the nature of the promise is one of the following:

- The delivery of a specified quantity of goods or services.
- A stand-ready obligation to provide an indefinite amount of goods or services during a specified period.
If the nature of the promise is to deliver a specified quantity of goods or services, the entity must determine whether each good or service is distinct, is substantially the same as the other goods or services, and has the same pattern of transfer to the customer as that of the other goods or services. If, on the other hand, the nature of the promise is to stand ready for a specified period, the entity must determine whether, for each increment of time, its promise of standing ready to provide the R&D or selling services is distinct, is substantially the same as its promise for each of the other increments of time, and has the same pattern of transfer to the customer as its promise for each of the other increments of time.

Contracts in the life sciences industry to perform R&D services appear in various forms. For example, some contracts may include a license to IP in addition to the R&D services. If it is determined that the license and the R&D services are both within the scope of ASC 606 but are not distinct promises (or if the customer already has control of a license and the entity's only promise in the contract is to provide R&D services), the series guidance may not apply to the combined performance obligation if the R&D services provided throughout the development period are cumulative in that each increment of service builds on and is dependent on the increments that precede it (i.e., such services would not be considered distinct within the context of the contract). This could be the case when the R&D activities performed on a particular day significantly modifies the results of R&D performed on previous days, resulting in each day's R&D services being highly dependent on and/or highly interrelated with other days' R&D activities. In such a case, the R&D services would generally be accounted for as a single combined performance obligation consisting of multiple activities that are not distinct, as opposed to a series of distinct increments of time or service. In certain other cases, R&D services may meet the criteria to be accounted for as a series, as illustrated in the example below.

**Example**

CRO enters into an arrangement with Pharma, the developer of a new drug compound, to perform daily R&D services for Pharma as needed during phase III clinical trials by giving Pharma access to clinical professionals. In exchange for the R&D services provided to Pharma, CRO will receive a daily fee per person and success-based milestone payments.

The activities to be performed may vary each day as CRO and Pharma work toward agreed-upon objectives in connection with the phase III clinical trials. While the activities may vary by day, they represent fulfillment activities associated with providing the daily R&D services and do not represent separate promises in the arrangement. Further, the CRO has determined that such services are readily available in the marketplace and are not cumulative because each day's research and corresponding results are not dependent on the prior day's research; thus, each day of services neither builds on nor is dependent on or interrelated with activities that precede it. That is, no day of services significantly affects either CRO's ability to fulfill another day of services or the benefit to Pharma of another day of services.

CRO determines that Pharma is a customer within the context of providing the services and therefore concludes that the services are within the scope of ASC 606. In addition, CRO determines that the services to be provided to Pharma meet the criteria in ASC 606-10-25-27(a) for recognition of revenue over time since the services performed during each increment of time contribute to Pharma's development of the drug compound and thereby allow Pharma to simultaneously receive and consume the benefits provided by CRO's performance as each task is performed.
### Nature of the Promise

CRO determines that the nature of its promise is to stand ready to provide daily R&D services as needed during phase III clinical trials. Accordingly, CRO must assess whether, for each increment of time, its promise of standing ready to provide the R&D services (1) is distinct, (2) is substantially the same as its promise for each of the other increments of time, and (3) has the same pattern of transfer to the customer as its promise for each of the other increments of time.

#### Distinct

Pharma benefits from each day of services on its own since the services contribute to Pharma’s development of the drug compound and are readily available in the marketplace. Consequently, CRO concludes that each increment of services is capable of being distinct.

In addition, CRO determines that each increment of services is distinct within the context of the contract. This is because each day of services (1) does not significantly modify or customize another day of services and (2) does not significantly affect CRO’s ability to fulfill another day of services or the benefit to Pharma of another day of services since the R&D services are not cumulative, as noted above.

#### Substantially the Same

CRO determines that for all of the increments of time during which R&D services are performed, its promise of standing ready to perform those services is substantially the same. While the specific tasks or services performed during each increment of time will vary, the nature of the overall promise to provide Pharma with daily R&D services remains the same throughout the contract term.

#### Same Pattern of Transfer

CRO determines that the services have the same pattern of transfer to Pharma because both criteria in ASC 606-10-25-15 are met. The criterion in ASC 606-10-25-15(a) is met because each distinct service meets the criteria in ASC 606-10-25-27 to be a performance obligation satisfied over time since Pharma simultaneously receives and consumes the benefits provided by CRO as CRO performs. The criterion in ASC 606-10-25-15(b) is met because the same measure of progress (in this case, a time-based output method) would most likely be used to measure the progress of CRO toward satisfying its promise to provide the daily R&D services.

### Conclusion

On the basis of the above, CRO concludes that the R&D services are a series and accounts for them accordingly.

A similar conclusion might be reached for outsourced selling services. For example, each day of selling services may meet the criteria to be accounted for as a series for the following reasons:

- The selling services are distinct because:
  - The customer can benefit from the sales force activities each day as the sales force promotes and sells the pharmaceutical products.
  - Each day (or increment) of selling services does not affect any other day (or increment) of selling services. That is, each day's services may not be modified or customized by another day's services, one day of services is not an input with another day of services that results in a combined output, and each day of services is not highly dependent on or interrelated with another day of services. That is, the entity providing the selling services can satisfy its promise to transfer selling services each day separately from a subsequent day of services.
• All increments (i.e., days) of the selling services are substantially the same (i.e., providing a comprehensive selling service). The volume of services may vary as a result of factors such as attrition of the sales representatives, the doctors’ offices visited, and the different selling activities conducted each day, but the nature of the promise is the same each day and the customer benefits from the services in the same manner each day.

• The customer simultaneously receives and consumes the benefits of having an outsourced sales force selling its pharmaceutical products. That is, the customer benefits from each increment of service (i.e., day, week, or month). In addition, if the contract were to be terminated, a third party would not need to reperform the selling services already provided since the customer would have already benefited from the sales that were made. As a result, each increment of service is distinct and is satisfied over time, and the same method (time elapsed) would most likely be used to measure the service provider’s progress toward complete satisfaction of the performance obligation to transfer each distinct service in the series to the customer.

**Q&A 2-16 Evaluating Whether a Promised Good or Service Is Immaterial in the Context of the Contract**

In April 2016, the FASB issued **ASU 2016-10**, which states that an entity “is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer.” This guidance should not be applied to a customer option to acquire additional goods and services that provides a customer with a material right in accordance with ASC 606-10-55-41 through 55-45.

**Question**

How should an entity evaluate whether a promised good or service is immaterial in the context of the contract?

**Answer**

ASU 2016-10 added ASC 606-10-25-16A and 25-16B, which provide the following guidance on immaterial promised goods or services:

<table>
<thead>
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<th>ASC 606-10</th>
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<tr>
<td><strong>25-16A</strong> An entity is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer. If the revenue related to a performance obligation that includes goods or services that are immaterial in the context of the contract is recognized before those immaterial goods or services are transferred to the customer, then the related costs to transfer those goods or services shall be accrued.</td>
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<tr>
<td><strong>25-16B</strong> An entity shall not apply the guidance in paragraph 606-10-25-16A to a customer option to acquire additional goods or services that provides the customer with a material right, in accordance with paragraphs 606-10-55-41 through 55-45.</td>
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</table>
In light of the wording in ASU 2016-10, stakeholders have asked about the framework an entity should use to identify a potential good or service that is immaterial in the context of the contract. The following have been considered, both of which we think are relevant to the assessment of whether a good or service is immaterial in the context of the contract:

- An entity may conclude that a potential good or service is immaterial in the context of the contract if the estimated stand-alone selling price of the potential good or service is immaterial (quantitatively) compared with the total consideration in the contract (i.e., the amount that would be allocated to such good or service is immaterial in the context of the contract).

- An entity may conclude that a potential good or service is immaterial in the context of the contract if it determines that the customer does not consider the potential good or service to be material to the contract (i.e., the entity would evaluate qualitative factors, including the customer's perspective, in determining whether a potential good or service is immaterial in the context of the contract).

For example, a medical device company might offer basic training or education services for equipment that it sells to a hospital. The value of this type of service may be immaterial (quantitatively) compared with the total consideration in the contract. Further, the basic training or education may not be a service that the customer considers to be material to the contract.

In addition, we think that when an entity performs an assessment to identify immaterial promised goods or services, it should also consider the guidance in ASU 2016-10 on customer options (i.e., potential material rights) as well as the SEC staff’s view of “material” as discussed in SAB Topic 1.M.

**Connecting the Dots**

As noted above, an entity should not apply the guidance in ASC 606-10-25-16A to a customer option to acquire additional goods or services that provides the customer with a material right. For example, a life sciences company may have a practice of providing customers with the ability to purchase 12 weeks of treatment at list price with an option to purchase an additional 12 weeks of treatment at a significantly discounted price if it is determined that the patient is benefiting from the treatment and additional treatment will be helpful. This type of discount on future treatments based on the efficacy of a drug during the initial treatment period may represent a material right. Similarly, arrangements that include the delivery of free drugs after a contractually defined purchase volume has been achieved may include a material right. Options that are deemed to represent material rights — and, therefore, a performance obligation — would result in a deferral of revenue associated with that performance obligation, as discussed below.

### 2.4.1 Customer Options for Additional Goods or Services (Material Rights)

An entity’s contract with a customer may give the customer a choice of whether to purchase additional goods or services; such a choice is typically referred to as an option for additional goods or services. Entities are required to identify options for additional goods or services because in certain circumstances, such options can lead to performance obligations. As explained in paragraph BC386 of ASU 2014-09, the FASB and IASB realized that it could be difficult to differentiate between (1) an option for additional goods or services that was paid for by the customer and (2) a marketing or promotional offer for which the customer did not pay. The first type of option for additional goods or services would be identified as a performance obligation to which consideration must be allocated in accordance with step 4 of the new revenue standard.
To help entities determine whether an option for additional goods or services is a performance obligation, the boards included the concept of a material right in the new revenue standard. If an entity determines that an option for additional goods and services is a material right, the option should be considered a performance obligation. However, an entity will need to use judgment to determine whether a material right exists.

The guidance in the new revenue standard describes a material right as an option that provides the customer an incremental discount beyond the discounts that are typically given. This concept of a material right stems from software revenue guidance under legacy U.S. GAAP in ASC 985-605, which provides that a deliverable in a contract should be accounted for separately if it is discounted by a significant and incremental amount with respect to both (1) that contract and (2) other similar contracts. However, a material right under the new guidance is slightly different in that the new revenue standard does not require the material right to be significant and incremental in relation to other discounts within the same contract.

When an option is identified as providing a customer with a material right, the option is identified as a performance obligation. A portion of the transaction price is then allocated to the option and recognized when (or as) (1) the future goods or services related to the option are provided or (2) the option expires.

Q&A 2-17  Whether the Assessment for Determining That a Contract Option Does or Does Not Provide a Material Right Is Only Quantitative

Question

Is the assessment of whether an option provides a customer with a material right only a quantitative assessment?

Answer

No. When determining whether a contract option provides a material right, entities should consider not only the quantitative significance of the option (i.e., the quantitative value of the benefit) but also previous and future transactions with the customer as well as qualitative factors. Specifically, qualitative features such as whether the rights accumulate (e.g., loyalty points) are likely to provide a qualitative benefit that may give rise to a material right.

Paragraph BC87 of ASU 2014-09 indicates that an entity should consider its customer’s valid expectations when identifying promised goods or services. A customer’s perspective on what constitutes a material right might consider qualitative factors (e.g., whether the right accumulates). Therefore, a numeric threshold alone might not determine whether a material right is provided by a customer option in a contract.

Refer to Examples 49, 50, 51, and 52 in ASC 606-10-55-336 through 55-356 for examples of how an entity would determine whether an option provides a customer with a material right.

The TRG discussed this issue in October 2014; a summary of the TRG’s discussion is available in TRG Agenda Paper 11. For additional information and Deloitte’s summary, see Appendixes D and E of Deloitte’s Revenue Roadmap.
2.4.2 Medicare Coverage Gap Discounts

As a result of the Patient Protection and Affordable Care Act, entities participating in Medicare Part D must provide Medicare beneficiaries in the Medicare coverage gap (or “donut hole”) with a 50 percent discount and annual increases to a maximum of 75 percent by 2020 in their Medicare prescription drug coverage.

Q&A 2-18 Recognizing Discounts Related to the Medicare Coverage Gap

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

Answer
No accounting literature directly addresses the accounting for discounts offered to individuals in the Medicare coverage gap. Before the adoption of ASC 606, an entity makes a policy election between two acceptable methods:

• “Specific identification” (or “point-of-sale”) model — An entity may apply the specific identification (or point-of-sale) model by estimating which prescription drug sales are attributable to individuals expected to be in the Medicare coverage gap and recognizing the related discount as a reduction of revenue for those sales. Under this model, the discount provided to an individual in the Medicare coverage gap is attributed to the specific party (i.e., the particular Medicare beneficiary) that would have been considered the payer. Accordingly, the discount is recognized in a manner similar to how the entity recognizes other discounts or pricing adjustments that would be attributed to other payers. In applying this method, the entity estimates when the coverage gap payment would be triggered on the basis of its product portfolio and sales volumes and records that estimate in the initial quarter that is affected.

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

An entity using either the specific identification model or the spread model for the discounts associated with sales attributed to the Medicare coverage gap should apply the method consistently.
We believe that under ASC 606, these same methods are generally supportable as follows:

- **Specific identification approach** — Under this approach, each individual patient purchase is a separate contract and cannot be combined with future “expected” but optional purchases. Accordingly, the consideration due and payable for each individual purchase is attributable to that individual sale. Coverage gap subsidies are viewed as a form of variable consideration attributable to individual sales of products to specific customers in accordance with ASC 606-10-32-6. As a result, the estimate of variable consideration specific to each individual transaction is recorded at the point of sale. The accounting outcome of this approach is generally consistent with that of the specific identification method described above. In a manner similar to the accounting for any form of variable consideration, an entity would estimate the variability (i.e., the occurrence or nonoccurrence of a future coverage gap discount in accordance with ASC 606-10-32-8) and apply the constraint guidance (ASC 606-10-32-11 and 32-12) before recognizing revenue when control of a purchased pharmaceutical drug is transferred into the distribution channel.

- **Material right approach** — Coverage gap subsidies constitute a material right in accordance with ASC 606-10-55-42. In effect, entities have entered into contractual arrangements with the U.S. government on behalf of Medicare-eligible patients in which the entities offer significant discounts on future purchases through the Medicare channel (i.e., all sales with Medicare-eligible patients throughout the year are “linked”). Under this approach, entities allocate a portion of the transaction price between current sales and the material right, which represents the discount to be provided on future sales to any Medicare-eligible patient within the coverage gap, and recognize the value of the material right in revenue when the coverage gap subsidies are used. This approach is inappropriate if rebates are expected to be made early in the year (as is the case for certain high-priced drugs) because it would be inappropriate to record a contract asset for what otherwise represents optional purchases.

### 2.4.3 Shipping and Handling Activities

Shipping and handling activities are often provided by life sciences entities as part of a revenue arrangement.

### Q&A 2-19 Considerations for Evaluating Shipping Terms and Determining the Accounting for Shipping and Handling Activities

**Question**

What considerations are relevant to the evaluation of shipping terms and the determination of how to account for shipping and handling activities performed by a vendor?

**Answer**

It is important to understand the shipping terms of an arrangement to determine when control of the good transfers to the customer. This is because the shipping terms often trigger some of the key control indicators (e.g., transfer of title and present right to payment). Therefore, a careful evaluation of shipping terms in a manner similar to their evaluation under legacy guidance is critical to the assessment of transfer of control. Common shipping terms include “free on board” (FOB) shipping point (title transfers to the customer at the entity’s shipping dock) and FOB destination (title transfers to the customer at the customer’s location).
Under legacy guidance, an entity applies a risks-and-rewards model that requires a careful evaluation of the entity’s involvement during the period of shipment in FOB shipping point fact patterns. That is, when the entity replaces lost or damaged products during shipping even though the shipping terms are FOB shipping point, it is often inappropriate under legacy guidance to recognize revenue upon shipment because the risks and rewards of ownership did not pass to the customer at the shipping point. Such practice should be reevaluated under the new revenue standard’s control-based model. While the fact that the entity has the significant risks and rewards of ownership is an indicator of control, that indicator may be overcome by the other indicators of control. As a result, it may be appropriate to recognize revenue upon shipment when the terms are FOB shipping point regardless of whether the entity retains the risks associated with loss or damage of the products during shipment.

When FOB shipping point fact patterns are reassessed and control is determined to transfer upon shipment, the seller should consider whether the risk of loss or damage that it assumed during shipping gives rise to another performance obligation (a distinct service-type obligation) that needs to be accounted for separately in accordance with the new revenue standard. For example, such risk may represent another performance obligation if goods are frequently lost or damaged during shipping.

Further, entities should consider the practical expedient under U.S. GAAP (ASC 606-10-25-18B, added by ASU 2016-10) that allows entities the option to treat shipping and handling activities that occur after control of the good transfers to the customer as fulfillment activities. Entities that elect to use this practical expedient would not need to account for the shipping and handling as a separate performance obligation. Instead, when the practical expedient is elected and revenue for the related good is recognized before the shipping and handling activities occur, the entity should accrue the costs of the shipping and handling activities at the time control of the related good is transferred to the customer (i.e., at the time of sale).

ASU 2016-10 also explains that shipping and handling activities performed before control of a product is transferred do not constitute a promised service to the customer in the contract (i.e., they represent fulfillment costs).

### 2.5 Determine the Transaction Price (Step 3)

In step 3 of the new revenue standard, an entity determines the “transaction price,” which, as stated in ASC 606-10-32-2, represents “the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.” Because the transaction price is an expected amount, estimates are inherently required. When determining the transaction price, an entity is required under ASC 606-10-32-3 to “consider the effects of all of the following”:

- “Variable consideration.”
- “Constraining estimates of variable consideration.”
- “The existence of a significant financing component in the contract.”
- “Noncash consideration.”
- “Consideration payable to a customer.”

The effects of these elements are particularly relevant to life sciences entities, as explained in the sections below.
2.5.1 Variable Consideration

Q&A 2-20 Examples of Variable Consideration

Question
What are examples of variable consideration in the life sciences industry?

Answer
ASC 606-10-32-6 explains that variable consideration may arise “because of discounts, rebates, refunds, credits, price concessions, incentives, performance bonuses, penalties, or other similar items” and that the promised consideration can vary “if an entity’s entitlement to the consideration is contingent on the occurrence or nonoccurrence of a future event” (e.g., when “a product [is] sold with a right of return or a fixed amount is promised as a performance bonus on achievement of a specified milestone”). In the life sciences industry, common forms of variable consideration include returns, chargebacks, rebates, cash and volume-based discounts, promotions, shelf stock adjustments, and other adjustments to revenue, as well as royalties, development-based milestones, and sales-based milestones.

Q&A 2-21 Methods of Estimating Variable Consideration

Question
Which methods should a life sciences entity use to estimate variable consideration?

Answer
Regardless of the form of variability or its complexity, once variable consideration is identified, an entity is required under ASC 606-10-32-8 to estimate the amount of variable consideration to determine the transaction price in a contract with a customer by using either the “expected value” method or the “most likely amount” method, “depending on which method the entity expects to better predict the amount of consideration to which it will be entitled.” As ASC 606-10-32-8 explains, the expected value is “the sum of probability-weighted amounts in a range of possible consideration amounts. An expected value may be an appropriate estimate of the amount of variable consideration if an entity has a large number of contracts with similar characteristics.” ASC 606-10-32-8 further states that the most likely amount is “the single most likely amount in a range of possible consideration amounts (that is, the single most likely outcome of the contract).”

In the life sciences industry, it may be appropriate for an entity to estimate development- and sales-based milestones by using the most likely amount method since the achievement of a milestone has only two possible outcomes (an entity either achieves the milestone or does not achieve it). Other forms of variable consideration may be estimated under the expected value method. For example, estimates of returns under the expected value method may take into account factors such as the following:

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

In addition to the factors listed above, the following factors may be relevant to the development of estimates of variable consideration in the form of chargebacks and rebates under the expected value method:

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

In applying the expected value method to these types of estimates, life sciences entities are not necessarily expected to develop complex modeling techniques to identify all possible outcomes of variable consideration. Although we think that it is appropriate for an entity to be pragmatic in deriving an estimate by using one of the required methods, we do not think that it is appropriate to use a method described as management’s best estimate as either the most likely amount or the expected value of variable consideration. Consequently, entities are encouraged to evaluate their current estimation approaches for variable consideration and document the basis for any conclusion that these approaches align with the estimation methods of ASC 606.

Q&A 2-22  Price Protection Arrangements

Life sciences entities sometimes enter into price protection arrangements, under which wholesalers are reimbursed for any difference between the current sales price and the lowest price offered during a specified subsequent period (e.g., one year).

**Question**

How should an entity consider the guidance on variable consideration when accounting for price protection arrangements?

**Answer**

Under legacy guidance, the amount of revenue recognized is generally limited to the amount that is not contingent on a future event (i.e., the sales price is “fixed or determinable” and no longer variable). Accordingly, a price protection arrangement under legacy guidance may result in a conclusion that the selling price was not fixed or determinable on the date of sale because of the possibility of future price concessions. Consequently, revenue in such an arrangement may not be recognized until reliable estimates can be established or the product is sold through to the end user (i.e., on a sell-through basis).
Under the new revenue standard, an entity must include some or all of an estimate of variable (or contingent) consideration in the transaction price (which is the amount to be allocated to each unit of account and recognized as revenue) when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of revenue in subsequent periods. In price protection arrangements, the transaction price would therefore include an estimate of expected price protection determined under either the expected value method or the most likely amount method (i.e., whichever method the entity expects to better predict the amount of consideration to which it will be entitled), with revenue recognized when control transfers to the distributor.

**Connecting the Dots**

Instead of providing a retroactive discount, price protection arrangements may be structured to provide a discount on future purchases if a life sciences company sells its products to another customer at a lower price during a specified subsequent period. In these circumstances, the entity should consider whether the price protection arrangement conveys a material right to buy products at a lower price in the future. If a material right is determined to exist, this would represent a separate performance obligation to which a portion of the transaction price would need to be allocated. If a material right does not exist (e.g., because the discount applies only to future purchases and is not based on the volume of past purchases), there would be no impact on current sales, and future sales would be recognized at the discounted prices.

**Q&A 2-23 Price Appreciation Rights**

In contrast to price protection arrangements created to benefit the customer for subsequently reduced prices, life sciences entities may have price appreciation clauses in contracts with customers that are created to benefit the entity. Price appreciation clauses may allow the entity to charge the customer for any increases that the entity may make during the year (e.g., as the difference between the old and new wholesale acquisition costs for the product multiplied by the number of units of the product still held by the customer in inventory). An entity should assess whether the potential price appreciation in contracts with such clauses should be accounted for as variable consideration to be included as an estimate in the transaction price or whether the price appreciation should be treated as a contract modification when the price change occurs under ASC 606-10-25-10 through 25-13.

**Question**

How should an entity consider the guidance on variable consideration when accounting for price appreciation rights?

**Answer**

In arrangements with price appreciation rights, the transaction price would include an estimate of expected price appreciation to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty about whether a price increase will occur is subsequently resolved. In these circumstances, a life sciences entity will need to consider its past business practices of raising prices and its intentions with respect to such increases. For any such estimates that are included in the transaction price, a life sciences entity will need to estimate the amount of inventory that the customer will have on hand at the time of the price increase, as well as any resulting “gross-to-net” deductions (e.g., chargebacks, rebates, returns, and other similar adjustments) that will increase as a result of the increase in the wholesale acquisition cost.
Q&A 2-24  New Product Launches With a Right of Return

Question

How should an entity consider the guidance on variable consideration when accounting for new product launches that include a right of return?

Answer

Under legacy guidance, life sciences entities are required to make a reasonable estimate regarding future returns to recognize revenue upon shipment of the product. ASC 605-15-25-3 indicates that the ability to make such an estimate depends on many factors and identifies a number of factors that may impair this ability (e.g., the susceptibility of the product to significant external factors, such as technological obsolescence or changes in demand; relatively long periods in which a particular product could be returned; the absence of historical experience with similar types of sales of similar products; and the absence of a large volume of relatively homogeneous transactions). Evaluating these factors for new product launches in the pharmaceutical industry could be even more challenging. The amount of historical information and evidence needed to support the estimates and assumptions regarding returns could be reduced depending on whether the product was (1) a modification of an existing product, (2) similar to other products in the market (i.e., an “analog”), or (3) a completely new product.

Under the new revenue standard, the uncertainty associated with whether a product may be returned is treated, for measurement purposes, consistently with the uncertainty associated with other variable consideration. That is, under ASC 606-10-55-25:

An entity should . . . determine the amount of consideration to which the entity expects to be entitled (that is, excluding the products expected to be returned). For any amounts received (or receivable) for which an entity does not expect to be entitled, the entity should not recognize revenue when it transfers products to customers but should recognize those amounts received (or receivable) as a refund liability. Subsequently, at the end of each reporting period, the entity should update its assessment of amounts for which it expects to be entitled in exchange for the transferred products and make a corresponding change to the transaction price and, therefore, in the amount of revenue recognized.

Obtaining sufficient evidence for new products may be difficult when the company does not have a relevant history for an analog or a clear competitive advantage that allows for more predictable sales. When using an analog to aid in the estimation of returns, life sciences entities are encouraged to document the basis for their conclusions that the analog is similar to the product being sold. Typically, this documentation should reflect that the analog is part of a similar therapeutic class, provides a similar mechanism of treatment, and targets similar customers and markets.

Q&A 2-25  Pay-for-Performance Arrangements

Pay-for-performance arrangements are becoming increasingly more common in the life sciences industry. Pay for performance in health care gives financial incentives to clinicians for better health outcomes. Clinical outcomes, such as longer survival, can be difficult to measure, so pay-for-performance systems usually measure process outcomes. Also known as “value-based purchasing,” this payment model rewards physicians, hospitals, medical groups, and other health care providers for meeting certain performance measures for quality and efficiency. It provides a disincentive to caregivers for poor outcomes, medical errors, or increased costs.
**Question**
How should an entity consider the guidance on variable consideration in the new revenue standard when accounting for pay-for-performance arrangements?

**Answer**
Under legacy guidance, life sciences entities are required to reasonably estimate future adjustments to the amounts billed for the product. If the vendor does not have a company-specific historical basis to estimate refunds, revenue is generally deferred until the close of the predetermined contingency period.

Under the new revenue standard, however, pay-for-performance arrangements represent another form of variable consideration. In a manner similar to the accounting in the examples above, a life sciences entity with these types of arrangements must include some or all of an estimate of variable consideration in the transaction price when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of cumulative revenue in subsequent periods.

**Q&A 2-26  Retroactive Payback Provisions**
In certain countries, companies are required to pay rebates to the country’s government health care system if domestic industry sales exceed specified thresholds in a given year. If the threshold is exceeded, the portion of the payback allocated to an individual company is based on that company’s current market share (or sales) in relation to the industry as a whole.

**Question**
How should an entity consider the guidance on variable consideration when accounting for a retroactive payback provision?

**Answer**
Under the new revenue standard, an entity would account for the retroactive payback provision as a retroactive rebate (i.e., variable consideration) and possibly use the expected value method to estimate it, subject to the constraint.

**Q&A 2-27  Volume Rebates**
A life sciences entity may offer its customers rebates or discounts on the pricing of products or services once specific volume thresholds have been met. That is, an entity may either retrospectively or prospectively adjust the price of its goods or services once a certain volume threshold has been met.

**Question 1**
Should an entity account for an offer to **retrospectively** lower the price per unit (once certain volume thresholds are met) as variable consideration (rather than as a customer option to be evaluated as a potential material right)?
Chapter 2 — Revenue Recognition

**Answer**

Yes. A volume rebate or discount that is *retrospectively* applied should be accounted for as variable consideration under ASC 606. In accordance with ASC 606-10-32-6, which specifically includes discounts and rebates as a form of variable consideration, the “promised consideration also can vary if an entity's entitlement to the consideration is *contingent on the occurrence or nonoccurrence of a future event*” (emphasis added).

**Question 2**

Should an entity account for an offer to *prospectively* lower the price per unit (once certain volume thresholds are met) as variable consideration (rather than as a customer option to be evaluated as a potential material right)?

**Answer**

No. When a volume rebate or discount is applied *prospectively*, entities will need to evaluate the facts and circumstances of each contract to determine whether the rebate or discount represents a material right and therefore should be accounted for as a performance obligation. As part of this evaluation, entities would consider whether the offer to the customer is at a price that would reflect the stand-alone selling price for that good or service, in accordance with ASC 606-10-55-43.

**Q&A 2-28  Discounts Provided to Group Purchasing Organizations**

Life sciences companies frequently enter into agreements with group purchasing organizations (GPOs) to provide discounts to hospitals that are affiliated with the GPOs. Distributors of the life sciences companies’ products then request reimbursement of the discounts provided to the life sciences companies’ hospital customers.

**Question**

How should a life sciences company account for discounts provided to GPOs?

**Answer**

In accordance with the new revenue standard, a life sciences company should treat these discounts as variable consideration and possibly use the expected value method to estimate the discounts, subject to the constraint.

In addition to providing these discounts, life sciences companies frequently pay administrative fees to GPOs to fund the expenses of GPO members. To determine the appropriate classification of these administrative fees as a reduction of revenue or as an increase to operating expense, a life sciences company should consider the relationships between the vendor, the GPO, and the GPO member to determine whether the GPO is a customer. For example, the company might consider the GPO to be a customer, and therefore may be required to reflect the fee as a reduction of revenue, if the GPO is a related party of the GPO member or if there is a mechanism to pass through the administrative fee from the GPO to the GPO member.
Connecting the Dots

Similar questions related to income statement classification may arise regarding payments made by life sciences companies to not-for-profit entities (NFPs) or other organizations that fund copay assistance programs to defray the cost of high-priced drugs. Specifically, there may be questions about whether these payments represent consideration paid to an indirect customer (e.g., because the contribution funds are ultimately used by patients to purchase the company’s products). While these payments may have been classified in expense under legacy guidance, life sciences companies are encouraged to evaluate their facts and circumstances to determine whether these payments represent a form of variable consideration under the new revenue standard.

In June 2018, the FASB issued ASU 2018-08, which clarifies the scope and accounting guidance for contributions received and contributions made. Specifically, the ASU indicates that its amendments are intended, in part, to help entities evaluate “whether transactions should be accounted for as contributions (nonreciprocal transactions) within the scope of [ASC 958] or as exchange (reciprocal) transactions subject to other guidance,” such as ASC 606. The ASU explains that while the issues it aims to address have been long-standing, “the amendments in [ASU 2014-09] place an increased focus on the issues because those amendments add new disclosure requirements and eliminate certain limited exchange transaction guidance that was previously contained in [ASC] 958-605.”

2.5.2 Constraining Estimates of Variable Consideration

Since revenue is one of the most important metrics to users of financial statements, the FASB and IASB and their constituents agreed that estimates of variable consideration are useful only to the extent that an entity is confident that the revenue recognized as a result of those estimates will not be subsequently reversed. Accordingly, as noted in paragraph BC203 of ASU 2014-09, the boards acknowledged that some estimates of variable consideration should not be included in the transaction price if the inherent uncertainty could prevent a faithful depiction of the consideration to which the entity expects to be entitled in exchange for delivering goods or services. Thus, the focus of the boards’ deliberations on a mechanism to improve the usefulness of estimates in revenue as a predictor of future performance was to limit subsequent downward adjustments in revenue (i.e., reversals of revenue recognized). The result of those deliberations is what is commonly referred to as the “constraint.”

ASC 606-10-32-11 and 32-12 describe the constraint and provide guidance on how it should be applied:

<table>
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<tr>
<th>ASC 606-10</th>
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<tr>
<td><strong>32-11</strong> An entity shall include in the transaction price some or all of an amount of variable consideration estimated in accordance with paragraph 606-10-32-8 only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.</td>
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</tbody>
</table>
In assessing whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur once the uncertainty related to the variable consideration is subsequently resolved, an entity shall consider both the likelihood and the magnitude of the revenue reversal. Factors that could increase the likelihood or the magnitude of a revenue reversal include, but are not limited to, any of the following:

a. The amount of consideration is highly susceptible to factors outside the entity's influence. Those factors may include volatility in a market, the judgment or actions of third parties, weather conditions, and a high risk of obsolescence of the promised good or service.

b. The uncertainty about the amount of consideration is not expected to be resolved for a long period of time.

c. The entity's experience (or other evidence) with similar types of contracts is limited, or that experience (or other evidence) has limited predictive value.

d. The entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions of similar contracts in similar circumstances.

e. The contract has a large number and broad range of possible consideration amounts.

Importantly, the constraint does not apply to sales- or usage-based royalties derived from the licensing of IP; rather, consideration from such royalties is only recognized as revenue at the later of when the performance obligation is satisfied or when the uncertainty is resolved (e.g., when subsequent sales or usage occurs). See Section 2.10 for additional discussion.

**Q&A 2-29 Factors for Determining Whether to Constrain Estimates of Variable Consideration**

**Question**

What factors may be relevant to a life sciences entity's determination of whether to constrain its estimates of variable consideration?

**Answer**

Inherent in ASC 606-10-32-12 are three key aspects of the assessment necessary for an entity to determine whether an estimate of variable consideration in a contract with a customer should be constrained in an entity's transaction price:

- The likelihood of a reversal in the cumulative amount of revenue recognized (i.e., a qualitative aspect).
- The magnitude (or significance) of the potential reversal in the cumulative amount of revenue recognized (i.e., a quantitative aspect).
- The threshold that triggers a constrained estimate (i.e., the use of “probable”).
The determination of whether to constrain estimates of variable consideration may require significant judgment depending on the nature of the revenue stream being estimated. For example, it may be unnecessary for an entity to constrain revenue on the sale of established pharmaceutical products to wholesalers since variable consideration (e.g., rebates, discounts) may not be highly susceptible to factors outside the entity’s influence (e.g., volatility in a market, the judgment or actions of third parties, a high risk of obsolescence), the uncertainty about the amount of consideration may be resolved in a shorter period, the entity may have significant experience with similar types of contracts or with contracts that have predictive value, and the range of price concessions is narrow.

In contrast, it may be necessary to constrain a significant portion of revenue on the sale of IPR&D, a nonfinancial asset, in exchange for future development milestones and royalties and sales-based milestones since the likelihood of reversal in the cumulative amount of revenue recognized could be high and the magnitude of the potential reversal could be significant. The uncertainty associated with revenue related to such a transaction 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.
- Both before and after regulatory approval, the amount of consideration to be received may be highly susceptible to factors outside the entity’s influence because success is predicated on the efforts of the party to which the IPR&D was sold.

Although the guidance on constraining estimates of variable consideration is intended to avoid significant downward adjustments in revenue after it has been recognized, we generally do not think that it would be appropriate to constrain 100 percent of an estimate of variable consideration. That is, we do not think that the factors in ASC 606-10-32-12 could be so significant that an estimate of variable consideration should be entirely constrained from the transaction price. This concept is different from a $0 estimate of variable consideration. A 100 percent constraint on an estimate of variable consideration that is not $0, however, would generally go against the measurement principle of ASC 606, which is to include in the transaction price the amount to which an entity expects to be entitled for its performance so that the entity can provide financial statement users a better prediction of future revenues.

While the above is a general interpretation, there are exceptions in the new revenue standard that may allow for a 100 percent constraint on an estimate of variable consideration. Example 25 in ASC 606-10-55 discusses an exception in which market-based factors are a significant driver of variability in the transaction price. Also, in paragraph BC415 of ASU 2014-09, the boards discuss their rationale for providing an exception for sales- or usage-based royalties in a license of IP.
Connecting the Dots

Milestone payments that are due upon regulatory approval are inherently based on factors outside the entity’s control. As a result, life sciences companies that use a most likely method to estimate variable consideration may conclude that the variable consideration associated with a regulatory approval milestone is $0 before regulatory approval. However, there may be certain cases in which a milestone earned upon regulatory approval becomes probable before the approval date. For example, when an authorized generic of an existing branded drug is under FDA review, an entity may determine before the actual approval date that approval is likely to occur. Contrast that with a new drug compound for which there is no competitor on the market. In this case, it may be more difficult to assert probability in advance of the actual approval date. In addition, in determining whether to recognize an approval-based milestone before approval occurs, entities are encouraged to consider how the judgments they make when applying the constraint guidance compare with the judgments they make when determining whether to capitalize “prelaunch inventory” since a probability assessment is required in each instance.1

2.5.3 Subsequent Changes in the Transaction Price

It is common for a life sciences entity to enter into a contract with a customer that entitles the life sciences entity to variable consideration in the event that the customer receives regulatory approval as a result of the R&D activities performed by the life sciences entity. Because the variable consideration is contingent on the customer’s receipt of regulatory approval, the life sciences entity is required to estimate the amount of variable consideration to include in the transaction price. Given the uncertainty of the regulatory approval process, the life sciences entity’s estimate of the variable consideration to which it will be entitled may be zero until a notification of regulatory approval is received.

When additional information on regulatory approval is received (i.e., approval notification or denial is received) after the end of the reporting period and before the date on which the financial statements are issued or are available to be issued, an entity should refer to the guidance in ASC 855 on accounting for subsequent events. Paragraph BC228 of ASU 2014-09 states the following:

The Boards noted that in some cases, an entity might make an estimate of the amount of variable consideration to include in the transaction price at the end of a reporting period. However, information relating to the variable consideration might arise between the end of the reporting period and the date when the financial statements are authorized for issue. The Boards decided not to provide guidance on the accounting in these situations because they noted that the accounting for subsequent events is already addressed in Topic 855, Subsequent Events, and IAS 10, Events after the Reporting Period.

ASC 855 distinguishes between recognized subsequent events (ASC 855-10-25-1) and nonrecognized subsequent events (ASC 855-10-25-3) as follows:

<table>
<thead>
<tr>
<th>ASC 855-10</th>
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<tr>
<td>25-1 An entity shall recognize in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements. See paragraph 855-10-55-1 for examples of recognized subsequent events.</td>
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</table>

1 While a probability assessment in a constraint analysis may give rise to conclusions similar to those resulting from a probability assessment in a prelaunch inventory analysis, the term “probable” is defined differently in each assessment. For purposes of determining the constraint under the new revenue standard, “probable” is defined in a manner consistent with the ASC 450 definition in that the future event or events are likely to occur. For purposes of assessing whether prelaunch inventory meets the definition of an asset, footnote 18 of FASB Concepts Statement 6 states that “[p]robable is used with its usual general meaning, rather than in a specific accounting or technical sense (such as that in FASB Statement No. 5, Accounting for Contingencies, par. 3), and refers to that which can reasonably be expected or believed on the basis of available evidence or logic but is neither certain nor proved.”
**ASC 855-10 (continued)**

**25-3** An entity shall not recognize subsequent events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after the balance sheet date but before financial statements are issued or are available to be issued. See paragraph 855-10-55-2 for examples of nonrecognized subsequent events.

However, ASC 855 does not provide direct guidance on how to account for additional information about regulatory approval or denial that is received after the end of the reporting period and before the date on which the financial statements are issued or are available to be issued. We believe that the conclusion to account for information received regarding the regulatory approval process as either a recognized or a nonrecognized subsequent event will be based on the facts and circumstances and may require significant judgment. Accordingly, entities are encouraged to consult with their accounting advisers.

### 2.5.4 Significant Financing Components

In certain contracts with customers, one party may provide a service of financing (either explicitly or implicitly) to the other. Such contracts effectively contain two transactions: one for the delivery of the good or service and another for the benefit of financing (i.e., what is in substance a loan payable or loan receivable). The FASB and IASB decided that an entity should account for both transactions included in a contract with a customer.

**ASC 606-10**

**32-15** In determining the transaction price, an entity shall adjust the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer or the entity with a significant benefit of financing the transfer of goods or services to the customer. In those circumstances, the contract contains a significant financing component. A significant financing component may exist regardless of whether the promise of financing is explicitly stated in the contract or implied by the payment terms agreed to by the parties to the contract.

In determining the transaction price, an entity adjusts the promised amount of consideration to determine the cash selling price of the good or service to be delivered and reflect the time value of money if the contract has a significant financing component. The direction of the financing component (i.e., whether financing is provided to the entity through an advance payment or to the customer through payments in arrears) is irrelevant to the assessment, and as a result of the adjustment to the transaction price, the entity could recognize interest expense or interest income.

However, ASC 606-10-32-18 provides a practical expedient under which an entity does not need to adjust the promised amount of consideration for the effects of a significant financing component “if the entity expects, at contract inception, that the period between when the entity transfers a promised good or service to a customer and when the customer pays for that good or service will be one year or less.”

**Q&A 2-30 Factors for Determining Whether a Significant Financing Component Exists**

Life sciences entities often receive advance payments for services. For example, payments are often required by CROs in advance of performing clinical trials, or by third-party manufacturers to secure manufacturing capacity.
Question
What factors may be relevant for life sciences entities to consider in determining whether there is a significant financing component in a contract with a customer?

Answer
Entities must use judgment in determining whether a significant financing component exists. However, ASC 606-10-32-17 notes that a contract with a customer would not have a significant financing component if certain factors exist. The table below describes the factors of greatest relevance to life sciences entities and examples of arrangements in which these factors may apply.

<table>
<thead>
<tr>
<th>Factor (ASC 606-10-32-17)</th>
<th>Example</th>
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<tr>
<td>“A substantial amount of the consideration promised by the customer is variable, and the amount or timing of that consideration varies on the basis of the occurrence or nonoccurrence of a future event that is not substantially within the control of the customer or the entity.”</td>
<td>Royalty arrangements, in which variability is provided to confirm the value of goods delivered.</td>
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| “The difference between the promised consideration and the cash selling price of the good or service (as described in paragraph 606-10-32-16) arises for reasons other than the provision of finance to either the customer or the entity, and the difference between those amounts is proportional to the reason for the difference. For example, the payment terms might provide the entity or the customer with protection from the other party failing to adequately complete some or all of its obligations under the contract.” | Customer withholds consideration until the achievement of a certain milestone and to protect against nonperformance.  
Customer required to pay up front to secure supply of a good. |

2.5.5 Noncash Consideration
When providing goods or services, an entity may receive noncash consideration from its customers (e.g., goods, services, shares of stock). It is not uncommon for companies in the life sciences industry to enter into revenue transactions with customers that involve receiving products from the customer as consideration (e.g., supplies). Step 3 requires entities to include the fair value of the noncash consideration in the transaction price. Paragraph BC248 of ASU 2014-09 states the FASB’s and IASB’s rationale for this requirement: “When an entity receives cash from a customer in exchange for a good or service, the transaction price and, therefore, the amount of revenue should be the amount of cash received (that is, the value of the inbound asset). To be consistent with that approach, the Boards decided that an entity should measure noncash consideration at fair value.” Further, in issuing ASU 2014-09 and IFRS 15, the boards included guidance stating that changes in the fair value of noncash consideration for reasons other than its form would be subject to the variable consideration constraint in ASC 606-10-32-11 through 32-13 (paragraphs 56 through 58 of IFRS 15).
The measurement date for noncash consideration is different under the new revenue standard. For example, legacy guidance generally requires an entity receiving customer equity instruments in lieu of cash consideration for goods or services provided to measure the fair value of the equity instruments when performance was complete (i.e., when the equity instruments vested). By comparison, ASC 606-10-32-21 requires an entity to measure the fair value of noncash consideration at contract inception. Further, the sequence of determining the fair value of noncash consideration is reversed under the new revenue standard. Specifically, ASC 606-10-32-21 and 32-22 introduce the concept that requires an entity to first look to measure the estimated fair value of the noncash consideration and then consider the stand-alone selling price of the goods or services promised to the customer only when the entity is unable to reasonably estimate the fair value of the noncash consideration. In contrast, under legacy guidance, an entity is required to first consider the fair value of the goods or services surrendered and then look to the fair value of the asset acquired (i.e., the fair value of the noncash consideration) only if it is more evident than the fair value of the goods or services surrendered.

2.5.6 Consideration Payable to a Customer

ASC 606-10-32-25 through 32-27 establish requirements related to “consideration payable to a customer.” Consideration payable to a customer includes cash amounts that an entity pays, or expects to pay, to the customer (or to other parties that purchase the entity’s goods or services from the customer). An entity should account for consideration payable to a customer as a reduction of the transaction price and, therefore, of revenue unless the payment to the customer is in exchange for a distinct good or service (typically resulting in the recognition of an asset or expense).

Q&A 2-31 Applicability of the Guidance on Consideration Payable to a Customer

Question

Do the requirements related to consideration payable to a customer apply to all payments by an entity to its customers?

Answer

An entity should assess the following payments to customers under ASC 606-10-32-25 to determine whether they are in exchange for a distinct good or service:

- Payments to customers that result from a contractual obligation (either implicitly or explicitly).
- Payments to customers that can be economically linked to revenue contracts with those customers.

While an entity is not required to separately assess and document each payment made to a customer, an entity should not disregard payments that extend beyond the context of a specific revenue contract with a customer. Rather, an entity should use reasonable judgment when determining how broadly to apply the guidance on consideration payable to a customer to determine whether the consideration provided to the customer is in exchange for a distinct good or service (and is therefore an asset or expense) or is not in exchange for a distinct good or service (and is therefore a reduction of revenue).

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2 ASC 606-10-32-25 states that consideration payable to a customer “also includes credit or other items (for example, a coupon or voucher) that can be applied against amounts owed to the entity (or to other parties that purchase the entity’s goods or services from the customer).” As amended by ASU 2018-07, ASC 606-10-32-25 further states that consideration payable to a customer “also includes equity instruments (liability or equity classified) granted in conjunction with selling goods or services (for example, shares, share options, or other equity instruments).”
Q&A 2-32  Presentation of Consideration Payable to a Customer

Question
When a transaction involves the customer’s supplying goods or services to the entity, should the entity account for the “net” consideration as revenue, or should the entity account for those goods or services separately (and, accordingly, increase the transaction price for the goods or services provided to the customer)?

Answer
It depends. The goods or services supplied by the customer should be accounted for separately if both of the following conditions are met:

- Those goods or services are “distinct.”
- The entity can reasonably estimate the fair value of the goods or services that it will receive (which may not correspond to any amount specified in the contract for those goods or services).

If both of these conditions are met, the fair value of the goods or services received from the customer should be accounted for in the same way the entity accounts for other purchases from suppliers (e.g., as an expense or asset). If any consideration payable to the customer with respect to those goods or services exceeds their fair value, the excess should be accounted for as a reduction of the transaction price.

If either or both of these conditions are not met, any consideration payable to the customer with respect to those goods or services should be accounted for as a reduction of the transaction price.

The examples below illustrate the application of this guidance.

**Example 1**
An entity sells goods to a customer for $10,000 and, as part of the same arrangement, pays that customer $1,000 to provide a service. If the service is determined to be distinct and its fair value can be reasonably estimated (as being, for example, $600), a portion of the contractually stated amount will be recognized as a reduction of the transaction price for the sale of goods to $9,600 ($10,000 minus the $400 payment made to the customer in excess of the fair value of the service received).

**Example 2**
An entity sells goods to a customer for $10,000 and, as part of the same arrangement, pays that customer $1,000 to provide a service. If the service is not determined to be distinct or its fair value cannot be reasonably estimated, the transaction price for the sale of goods will be reduced to $9,000 ($10,000 minus the full amount payable to the customer).
Connecting the Dots

Questions related to income statement classification may arise about payments made by a pharmaceutical manufacturer and a wholesaler in accordance with a distribution service agreement. Under such an agreement, the wholesaler performs certain distribution and logistics services for the manufacturer, such as providing the manufacturer with periodic reports of inventory on hand and inventory sold through to the wholesaler's customers during the period, in exchange for inventory management fees. Although described as fees for specific services outlined in the agreement, such costs are typically classified as a reduction of revenue by the manufacturer because the fee paid to the wholesaler is not in exchange for distinct goods or services transferred to the manufacturer.

2.6 Allocate the Transaction Price to the Performance Obligations (Step 4)

In step 4 of the new revenue standard, an entity allocates the transaction price to each of the identified performance obligations. For a contract containing more than one performance obligation, the allocation is generally performed on the basis of the relative stand-alone selling price of each distinct good or service.

As discussed in Deloitte’s Revenue Roadmap, there are exceptions that allow an entity to allocate a disproportionate amount of the transaction price to a specific performance obligation. For example, an entity may allocate a discount to a single performance obligation rather than proportionately to all performance obligations if certain factors indicate that the discount is related to a specific performance obligation.

In addition, in arrangements that include a license of IP along with ongoing services (e.g., R&D or manufacturing) that represent distinct performance obligations, an entity is required to allocate the total transaction price between the license and the services. If a history of selling the services or IP separately does not exist, the entity will need to estimate the stand-alone selling price of each performance obligation by using one of the following methods:

- **Adjusted market assessment approach** — Under this method, an entity considers the market in which the good or service is sold and estimates the price that a customer in that market would be willing to pay. In addition, the entity considers a competitor’s pricing for similar goods or services as adjusted for specific factors such as position in the market, expected profit margin, and customer-specific or geography-specific conditions. For example, a life sciences company may need to consider the specific rights associated with the license, the stage of development of the underlying IP, and the projected cash flows over the license period. Regarding the R&D services, prices of similar services offered in the marketplace may be considered.

- **Expected cost plus a margin** — Under this method, an entity estimates the stand-alone selling price by considering the costs incurred to produce the product or service plus an adjustment for the expected margin on the sale. This method may be appropriate for an entity to use when it determines the selling price of R&D or manufacturing services by considering the level of effort necessary to perform the services.

- **Residual approach** — This approach may only be used if the entity sells the same good or service to different customers for a broad range of amounts, making the consideration highly variable, or the entity has not yet established a price for that good or service and the good or service has not previously been sold. Under this method, the entity deducts the estimated stand-alone selling price of other goods and services in the contract from the total transaction price to determine the stand-alone selling price of the remaining goods and services.
In many other respects, the allocation model under the new revenue standard may be similar to the model under legacy guidance, except for the new revenue standard's elimination of the selling price hierarchy required under legacy guidance. For certain life sciences companies, however, the allocation model under the new revenue standard may result in differences as a result of the elimination of the “contingent cap” concept. Specifically, under legacy guidance, the allocation of arrangement consideration to delivered items is limited to the amount of revenue that is not contingent on the delivery of future items. The new revenue standard does not include this same contingent cap. As a result, the timing of revenue recognition under the new revenue standard may be accelerated as compared with its timing under legacy guidance.

**Example 2-1**

A medical device company sells infusion pumps and intravenous solutions (consumables). In accordance with the company's contracts with customers, title to the pumps is transferred to the customer for free when the pumps are sold in conjunction with a minimum commitment for the purchase of consumables. Assume that the pumps and solutions are considered separate performance obligations.

Under legacy guidance, because the consideration to be received for one of the deliverables in the arrangement (i.e., equipment) is contingent on the sale of other deliverables in the arrangement (i.e., consumables), the medical device company would limit recognition of revenue for the delivered element up to the amount of consideration that is not contingent on the future sales. In this case, because the pump is provided to the customer for free and all of the consideration from the arrangement is contingent on the sale of disposables, the company would not recognize revenue when the pump is delivered to the customer. Under the new revenue standard, however, the company would estimate the amount of consideration to which it expects to be entitled and allocate the consideration on a relative stand-alone selling price basis to each separate performance obligation.

### 2.7 Determine When to Recognize Revenue (Step 5)

In a manner consistent with the core principle of the new revenue standard — “an entity shall recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services” (emphasis added) — step 5 focuses on recognition (i.e., when it is appropriate to recognize revenue).

The new standard requires an entity first to determine, at contract inception, whether control of a good or service is transferred over time; if so, the entity would recognize the related revenue over time in a manner consistent with the transfer of the good or service over time to the customer. This method is similar to the percentage-of-completion and proportional-performance methods in practice under legacy guidance. If the entity cannot conclude that control is transferred over time, control is considered to be transferred at a point in time. As a result, the entity must determine at what specific point in time to recognize the related revenue. While generally speaking, goods are transferred at a point in time and services are transferred over time, this is not the case in all circumstances. Some of the more common questions that life sciences entities have faced when considering step 5 are described below.
Q&A 2-33  Determining Whether to Recognize Revenue Over Time or at a Point in Time

Question
Contract manufacturing is common in the life sciences industry. Should entities that are delivering goods (e.g., contract manufacturers and other entities in customer manufacturing arrangements) recognize revenue over time or at a particular point in time?

Answer
It depends. Entities should carefully analyze the contractual arrangement in accordance with the three criteria in ASC 606-10-25-27 to determine whether the promise in the contract to construct and transfer goods to the customer is a performance obligation that will be satisfied over time or at a point in time.

If an entity's obligation to produce a customized product meets one of the criteria in ASC 606-10-25-27 for revenue recognition over time (e.g., the entity's performance does not create an asset with an alternative use, and the entity has an enforceable right to payment for performance completed to date), revenue related to that product would be recognized as the product is produced, not when the product is delivered to the customer.

For example, an entity that has a contract with an original equipment manufacturer (OEM) to produce a customized part for the OEM's product would meet the criteria for revenue recognition over time if the customized part has no alternative use other than as a part for the OEM's product and, as stated in ASC 606-10-25-29, the entity has an enforceable right to payment for performance completed to date "at all times throughout the duration of the contract." ASC 606-10-25-28 and 25-29 as well as ASC 606-10-55-8 through 55-15 provide detailed guidance on whether an asset has an alternative use to the entity and whether an entity has an enforceable right to payment for performance completed to date. An entity would need to carefully analyze the contractual arrangements and the specific facts and circumstances to determine whether those criteria are met.

If the entity concludes that revenue should be recognized over time, it would then be required to select a method of recognizing revenue over time that most faithfully depicts the entity's performance to date for producing the product. Therefore, contract revenue should be recognized as revenue when the entity performs (i.e., the products are produced) rather than when the products are delivered to the customer.

In certain contract manufacturing arrangements of life sciences entities, inventory that is being manufactured has no alternative use (e.g., because the product cannot be redirected to another customer), and the contract terms provide the right to payment for performance completed to date in an amount that approximates the selling price of the work in process (e.g., recovery of the costs incurred plus a reasonable profit margin) if the contract is canceled. In these arrangements, revenue should be recognized over time as inventory is manufactured.
Entities may need to use judgment when evaluating some of these arrangements (e.g., when contracts are silent or unclear about whether a right to payment exists). We believe that when a contract's written terms do not specify the entity's right to payment upon contract termination, an enforceable right to payment is presumed not to exist. However, if the contract with the customer does not specify by its written terms the entity's right to payment upon contract termination and the entity asserts that it has an enforceable right to payment for performance completed to date, we would expect the entity to:

- Support its assertion on the basis of legislation, administrative practice, or legal precedent that confers upon the entity a right to payment for performance to date, as stated in ASC 606-10-55-14(a). This analysis would need to demonstrate that an enforceable right to payment (as defined by ASC 606) exists in the relevant jurisdiction. The fact that the entity would have a basis for making a claim against the counterparty in a court of law would not be sufficient to support the existence of an enforceable right to payment.

- Assess whether relevant legal precedent indicates that similar rights to payment for performance completed to date in similar contracts have no binding legal effect, as stated in ASC 606-10-55-14(b).

Q&A 2-34  Impact of Shipping Terms on Revenue Recognition Over Time

Question

Do shipping terms in a contract that require a customer to pay only at a specific point in time (e.g., FOB destination) preclude the contract from meeting the criterion in ASC 606-10-25-27(c) for revenue recognition over time (specifically, the enforceable right to payment condition)?

Answer

No. The guidance in ASC 606-10-55-12 makes clear that an enforceable right to payment “need not be a present unconditional right to payment” and that an entity may have “an unconditional right to payment only . . . upon complete satisfaction of the performance obligation.” In these circumstances, the guidance states, “an entity should consider whether it would have an enforceable right to demand or retain payment for performance completed to date if the contract were to be terminated before completion for reasons other than the entity’s failure to perform as promised” (emphasis added).

When a contract’s shipping terms require an entity’s customer to pay only at a specific point in time (e.g., FOB destination), the possibility that the entity will not be paid if the goods are lost in shipment would represent “the entity’s failure to perform as promised” and should be disregarded in the entity’s assessment of whether the performance obligation meets the criterion in ASC 606-10-25-27(c) for revenue recognition over time (i.e., when an entity is assessing whether it has an enforceable right to payment, it should presume that it will perform as promised and that the goods will be delivered). Accordingly, the conclusion that the entity has an enforceable right to payment is not precluded when the contract's payment terms require payment only at specific points in the production or delivery process. Those payment terms may be overruled by contractual rights that give the entity an enforceable right to demand or retain payment (if the entity performs as promised). Therefore, the fact that the customer would not be required to pay for the goods if they were lost in transit would not, by itself, preclude the contract from meeting the criterion in ASC 606-10-25-27(c) for revenue recognition over time.
Q&A 2-35  Selecting a Measure of Progress Toward Complete Satisfaction of a Performance Obligation

When a performance obligation is satisfied over time, an entity must select a measure of progress (e.g., time elapsed, labor hours, costs incurred) to depict its progress toward complete satisfaction of that obligation.

In accordance with ASC 606-10-25-33, appropriate methods of measuring progress include:

- **Output methods** — ASC 606-10-55-17 states that output methods “recognize revenue on the basis of direct measurements of the value to the customer of the goods or services transferred to date relative to the remaining goods or services promised under the contract.” These methods include “surveys of performance completed to date, appraisals of results achieved, milestones reached, time elapsed, and units produced or units delivered.”

- **Input methods** — ASC 606-10-55-20 states that input methods “recognize revenue on the basis of the entity's efforts or inputs to the satisfaction of a performance obligation (for example, resources consumed, labor hours expended, costs incurred, time elapsed, or machine hours used) relative to the total expected inputs to the satisfaction of that performance obligation.”

In discussing the selection of a measure of progress, paragraph BC164 of ASU 2014-09 states:

The [FASB and IASB] decided that, conceptually, an output measure is the most faithful depiction of an entity's performance because it directly measures the value of the goods or services transferred to the customer. However, the Boards observed that it would be appropriate for an entity to use an input method if that method would be less costly and would provide a reasonable proxy for measuring progress.

Many CROs recognized revenue over time by using either input or output methods under legacy guidance.

**Question**

Does the statement in paragraph BC164 of ASU 2014-09 mean that it is preferable for an entity to use an output method when measuring progress toward complete satisfaction of a performance obligation?

**Answer**

No. As stated in paragraph BC159 of ASU 2014-09, an entity does not have a free choice in selecting an appropriate method of measuring progress toward complete satisfaction of a performance obligation but should exercise judgment in identifying a method that fulfills the stated objective in ASC 606-10-25-31 of depicting an entity's performance in transferring control of goods or services promised to a customer (i.e., the satisfaction of the performance obligation).
Neither an input method nor an output method is preferred since each has benefits and
disadvantages that will make it more or less appropriate to the facts and circumstances of
each contract. While an output method is, as stated in paragraph BC164 of ASU 2014-09,
conceptually preferable in a general sense, an appropriate measure of output will not always be
directly observable; and sometimes, an apparent measure of output will not in fact provide an
appropriate measure of an entity's performance. Information needed to apply an input method
is more likely to be available to an entity without undue cost, but care should be taken to ensure
that any measure of an entity's inputs used is reflective of the transfer of control of goods or
services to the customer.

Considerations that may be relevant to the selection of a measure of progress include the
following:

• An output method would not provide a faithful depiction of the entity’s performance
  if the output selected fails to measure some of the goods or services transferred to
  the customer. For example, a units-of-delivery or a units-of-production method may
  sometimes understate an entity’s performance by excluding work in progress that is
  controlled by the customer. (See paragraph BC165 of ASU 2014-09.)

• An input method may better reflect progress toward complete satisfaction of a
  performance obligation over time when (1) the performance obligation consists of a series
  of distinct goods or services that meets the criteria in ASC 606-10-25-14(b) to be treated
  as a single performance obligation and (2) the effort required to create and deliver the first
  units is greater than the effort to create the subsequent units because of the effect of a
  “learning curve” of efficiencies realized over time. (See paragraph BC314 of ASU 2014-09.)

• An entity applying an input method must exclude from its measure of progress the costs
  incurred that (1) do not contribute to the entity’s progress in satisfying a performance
  obligation (e.g., the costs of unexpected amounts of wasted materials) and (2) are not
  proportionate to the entity’s progress in satisfying the performance obligation (e.g., the
  cost of obtaining goods from a vendor that accounts for most of the product’s cost). (See
  ASC 606-10-55-21.)

Connecting the Dots

In the life sciences industry, CROs often incur out-of-pocket expenses and “pass-through costs”
related to payments made to investigators (physicians) who participate in the clinical studies
being conducted. Under the new revenue standard, if the CRO activity is part of a combined
performance obligation, these costs should generally be included in a CRO’s measure of
progress when a cost-based input measure is used to recognize revenue over time.

Q&A 2-36  Straight-Line Measure of Progress

Question

Can an entity default to a straight-line measure of progress on the basis of the passage of time?

Answer

No. While ASC 606-10-55-16 through 55-21 provide guidance on when an entity would use
an input or output method in measuring progress toward the complete satisfaction of a
performance obligation, the guidance does not prescribe the use of either method. However,
an entity does not have a free choice when selecting a measure of progress. While an entity
may use either type of method, the actual method selected should be consistent with the
clearly stated objective of depicting the entity’s performance (i.e., the entity’s satisfaction of its performance obligation in transferring control of goods or services to the customer). Although ASC 606 does not permit an entity to default to a straight-line measure of progress on the basis of the passage of time (i.e., because a straight-line measure of progress may not faithfully depict the pattern of transfer), ASC 606 does not prohibit the use of a straight-line measure of progress, and such a time-based method may be reasonable in some cases depending on the facts and circumstances. Sometimes, for example, the nature of the entity’s promise in a contract is to “stand ready” for a period rather than to provide the goods or services underlying the obligation (i.e., to perform on a joint steering committee and/or provide regulatory approval assistance when necessary). In the case of a stand-ready promise, the customer obtains (i.e., receives and consumes) a benefit from the assurance that a service or resource is available (“standing ready”) when and if needed or desired. For a stand-ready obligation that is satisfied over time, an entity may measure progress toward complete satisfaction of the performance obligation by using one of various methods, including time-based, input, and output methods. An entity would need to use judgment to select an appropriate measure of progress on the basis of the arrangement’s particular facts and circumstances.

Q&A 2-37  Multiple Measures of Progress Toward Complete Satisfaction of a Performance Obligation

CROs often provide multiple services for their customers (pharmaceutical and biotechnology entities). For example, CROs may help design studies, recruit investigators (physicians), recruit patients, help manage clinical trials, monitor safety, and write reports on study results.

Assume that a CRO concludes that its contract with a biotechnology customer contains a single performance obligation (i.e., in the context of the contract, the various services to be performed are not separable) and that the CRO concludes that the performance obligation is satisfied over time. Consequently, the CRO is required to identify an appropriate measure to depict progress toward complete satisfaction of its performance obligation (see ASC 606-10-25-31 through 25-37).

Question
When a single performance obligation satisfied over time consists of multiple promised goods or services, or both, can multiple measures of progress be used to depict an entity’s progress toward complete satisfaction of that performance obligation?

Answer
No. ASC 606-10-25-32 states that an entity should apply a single measure of progress for each performance obligation. This applies even when that single performance obligation is made up of a number of goods or services.

Selecting a measure of progress may be challenging when a single performance obligation contains multiple goods or services or has multiple payment streams. Regardless of the number of goods, services, or payment streams in a performance obligation, an entity is required to identify a single measure of progress that appropriately depicts its progress toward complete satisfaction of the performance obligation.
Connecting the Dots

Under legacy guidance, some CROs applied input methods while others applied output methods, with outputs based on different measures of progress. The new revenue standard requires an entity to identify a single measure of progress that appropriately depicts its progress toward complete satisfaction of the performance obligation. As a result, CROs have generally concluded that input measures should be used under ASC 606.

2.8 Consignment Arrangements

Although physical possession is an indicator that control has transferred to the customer, ASC 606-10-25-30(c) cautions that there are some arrangements in which physical possession may not be indicative of control. One example is a consignment arrangement.

Consignment arrangements occasionally exist in the life sciences industry (e.g., a medical device may be delivered to a hospital under a consignment arrangement until the device is needed for a surgery). Under ASC 606, the accounting for consignment arrangements may be consistent with legacy guidance if control of the products delivered to a consignee does not transfer until the consignee sells the products to a third party.

2.9 Government Vaccine Stockpile Programs

In August 2017, the SEC issued an interpretive release to update previously issued guidance on accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into stockpiles related to the Vaccines for Children Program or the Strategic National Stockpile.

The update was provided to bring existing guidance into conformity with ASC 606. Under the guidance, vaccine manufacturers should recognize revenue when vaccines are placed into U.S. government stockpile programs because control of the vaccines has been transferred to the customer. However, these entities also need to evaluate whether storage, maintenance, and shipping and handling activities of vaccine stockpiles are separate performance obligations. The guidance in the 2017 release applies only to the vaccine stockpile programs discussed in that release and is not applicable to any other transactions.

In November 2017, the FASB issued ASU 2017-14, which rescinds certain SEC guidance in legacy U.S. GAAP and codifies in ASC 606-10-S25-1 the text of the 2017 release.

2.10 Licensing

Under the new revenue standard, the framework used to account for licensing of IP is essentially the same as the framework used to account for a sale of goods or services. That is, the five-step model is generally applied to licensing transactions as well. However, licensing of IP can take many forms, and the economics and substance of such transactions can often be difficult to identify. Determining how to account for licensing transactions will often depend on the specific facts and circumstances and will require the exercise of professional judgment. To help preparers exercise such judgment, the new revenue standard provides supplemental guidance on recognizing revenue from contracts related to the licensing of IP to customers. The scope of the guidance includes all licenses that provide a customer with rights to IP, except for certain software hosting arrangements.
In the evaluation of how to account for a licensing transaction under the new revenue standard, it is important for an entity to consider each of the five steps in the model (although, as discussed below, certain exceptions are provided for licensing transactions). Specifically, an entity will need to do each of the following:

- **Step 1: Identify the contract with the customer** — This step includes evaluating the enforceable rights and obligations (including implicit rights) of each party to the contract and determining whether amounts under the contract are collectible.

- **Step 2: Identify the performance obligation under the contract** — This includes determining whether the entity's obligation to transfer a license to a customer results in (1) a single promise that will be satisfied (i.e., a single performance obligation) or (2) multiple performance obligations. This step could also involve determining whether the license of IP is the predominant element in the arrangement.

- **Step 3: Determine the transaction price** — This includes identifying and, potentially, measuring and constraining variable consideration.

- **Step 4: Allocate the transaction price** — This includes considering whether the residual method could be used for determining the stand-alone selling price of one (or a bundle) of the performance obligations.

- **Step 5: Determining when control of the license is transferred to the customer** — This includes determining whether the license is transferred at a point in time (for a right to use IP) or over time (for a right to access IP).

Some of the key judgments an entity will need to make are likely to be in connection with step 2 (identify the performance obligations) and step 5 (recognize revenue) of the model. As part of step 2, an entity will need to evaluate license restrictions (and changes in any such restrictions) when determining whether the restrictions merely define the licenses (which may be the case when the restrictions are related to time or geography) or, in effect, give rise to multiple performance obligations (which may be the case when the restrictions change over the license period and require the entity to transfer additional rights to the customer).

As part of step 5, when an entity is determining whether it has granted a customer a right to use or a right to access its IP, it will need to (1) assess the nature of the promised license to determine whether the license has significant stand-alone functionality and (2) evaluate whether such functionality can be retained without ongoing activities of the entity. For licenses with significant stand-alone functionality, ongoing activities of the entity providing the license do not significantly affect the license's functionality (i.e., its utility). However, certain licenses do not have significant stand-alone functionality and require ongoing activities from the entity to support or maintain the license's utility to the customer. The nature of an entity's license of IP will determine the pattern of transfer of control to the customer, which is either at a point in time (if the customer is granted a right to use the IP) or over time (if the customer is granted a right to access the IP).
Connecting the Dots

It is common in the life sciences industry for an entity to transfer a license of IP along with R&D services to the customer as a single performance obligation. The license may not be capable of being distinct without the R&D services. That is, the R&D services performed by the entity may be novel, requiring the entity to provide the R&D services for the customer to benefit from the license. In determining when revenue should be recognized for the single performance obligation with two promised goods (the delivery of the license and R&D services), the entity must determine whether the single performance obligation is satisfied over time or at a point in time. In this type of transaction, the criteria in ASC 606-10-25-27(a) and (b) for recognizing revenue over time may be met. The entity can conclude that the criterion in ASC 606-10-25-27(a) is met if it determines that the work that it has completed to date (related to the R&D services) would not need to be substantially reperformed by another entity if the other entity were to step in to fulfill the remaining performance obligation to the customer (since this would mean that the customer simultaneously receives and consumes the benefits provided by the entity’s performance of the R&D services as the entity performs those services). In addition, the entity can conclude that the criterion in ASC 606-10-25-27(b) is met if it determines that (1) the customer obtains control of the license (i.e., the customer has the ability to direct the use of, and obtain substantially all of the remaining benefits from, the license) and (2) the R&D services provided will simultaneously enhance the license.

For licensing transactions in which consideration is tied to the subsequent sale or usage of IP, the new revenue standard provides an exception to the recognition principle that is part of step 5 (i.e., recognize revenue when or as control of the goods or services is transferred to the customer). Under this sales- or usage-based royalty exception, an entity would not estimate the variable consideration from sales- or usage-based royalties. Instead, ASC 606-10-55-65 requires an entity to recognize revenue associated with a sales- or usage-based royalty promised in exchange for a license of IP when (or as) the later of the following events occurs:

a. The subsequent sale or usage occurs.
b. The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Connecting the Dots

In the application of the sale- or usage-based royalty exception in ASC 606-10-55-65, it would not be appropriate for an entity to omit sales- or usage-based royalties from its financial statements merely because the associated sales data were received after the end of the reporting period or were not received when the financial statements were issued or available to be issued.

Some of the more common questions that life sciences entities have faced when considering the licensing guidance of the new revenue standard are discussed below.
Q&A 2-38  Determining Whether the Sales- or Usage-Based Royalty Exception Applies to an In-Substance Sale of IP

Question
An entity may license IP to a customer under an arrangement that gives the customer exclusive use of the IP for a period that is substantially the same as the IP’s useful life. Is this type of arrangement within the scope of (1) the licensing implementation guidance in ASC 606-10-55-54 through 55-65B or (2) the general recognition and measurement model in the new revenue standard, which could result in a different pattern of revenue recognition? Specifically, does the sales- or usage-based royalty exception apply to an in-substance sale of IP?

Answer
The FASB considered, but rejected, expanding the scope of the royalty recognition constraint because of complexities in legal differences between a sale of IP and a license of IP. We generally believe that the legal form of the transaction will determine which revenue accounting guidance (i.e., the guidance on estimating royalties or the guidance on applying the royalty recognition constraint) is applicable.

Q&A 2-39  Distinguishing Between an Attribute of a License and an Additional Promise

A contract with a customer may contain provisions that limit the customer’s use of a license of IP to a specific period, a specific geographical region, or a specific use. For example, an entity may license drug distribution rights to a customer that can be (1) used for three years, (2) made available only to consumers in North America, and (3) used only for a specific drug indication. Often, such restrictions will be attributes of the license. That is, the restrictions will define the rights the customer has under the license. However, some restrictions, or changes in restrictions over time, will require an entity to transfer additional rights to a customer. Specifically, the amendments in ASU 2016-10 clarify that (1) certain contractual provisions indicate that an entity has promised to transfer additional rights (i.e., an additional license) to a customer and (2) promises to transfer additional rights should be accounted for as separate performance obligations.

Question
How should a life sciences entity determine whether contractual provisions represent an attribute of a license or an additional promise?

Answer
The determination of whether contractual provisions related to a license of IP represent an additional promise may require significant judgment. Contractual provisions (restrictions) that define the scope of a license of IP that has already been transferred to a customer would generally not be accounted for as a separate performance obligation. For example, a restriction that limits the use of a license to a five-year period would be an attribute of the single license. However, contractual provisions that define additional rights that will be transferred at a future date would generally be accounted for as a separate performance obligation, as illustrated in the example below.
Example

An entity transfers to a customer a two-year license of IP that can be used only in Jurisdiction A during year 1 but can be used in both Jurisdiction A and Jurisdiction B during year 2. In this example, the customer does not obtain control of the license in Jurisdiction B until year 2. That is, in year 2, the entity must transfer additional rights that entitle the customer to use the license in Jurisdiction B. Although the entity transfers the license to use the IP in Jurisdiction A at the beginning of year 1, the entity must still fulfill a second promise to deliver the license to use the IP in Jurisdiction B in year 2. Although the license of IP obtained by the customer in year 1 may be the same license of IP that will be used in year 2 (i.e., the customer currently controls the right to use or access the IP), the customer is precluded from using and benefiting from that license in Jurisdiction B until year 2. The obligation to transfer additional rights to the customer at the beginning of year 2 should be identified as an additional performance obligation under the contract with the customer.

Q&A 2-40  Functional Versus Symbolic IP

In determining whether to recognize revenue from a license of IP over time or at a point in time, an entity needs to determine the nature of the licensing arrangement. The nature of the arrangement is determined on the basis of the entity’s promise to the customer and whether that promise (1) provides access to the IP throughout the license term (i.e., “right to access”) or (2) provides a right to use the IP as it exists at the point in time when control of the license is transferred to the customer (i.e., “right to use”). Revenue from a license that grants a right to access an entity’s IP is recognized over time since the customer simultaneously receives and consumes the benefits of the entity’s IP throughout the license periods (i.e., meets the requirement in ASC 606-10-25-27(a)). Revenue from a license that grants a right to use an entity’s IP is recognized at the point in time when control of the license is transferred to the customer.

To assist in the evaluation of whether the license provides the customer with a right to access or right to use the entity’s IP, the new revenue standard distinguishes between two types of IP: (1) functional and (2) symbolic.

Question

In the life sciences industry, are most licenses of IP of a functional or symbolic nature? What impact does the nature of a license have on the timing of revenue recognition?

Answer

Examples of licenses of functional IP could include software, drug compounds and formulas, and completed media content. In accordance with ASC 606-10-55-62, the nature of a license to functional IP that is distinct will provide a customer with the right to use an entity’s IP (i.e., point-in-time revenue recognition) unless (1) the entity’s ongoing activities that will not transfer promised goods to the customer (i.e., those not deemed to be additional promised goods to the customer) will significantly change the utility of the license and (2) the customer is contractually or practically required to use the updated IP once available. If these criteria are met, the nature of the license is a right to access the entity’s IP (i.e., a license for which revenue is recognized over time). As discussed in paragraph BC58 of ASU 2016-10, the FASB expected that at the time of issuance of ASU 2016-10, the criteria in ASC 606-10-55-62 “will be met only infrequently, if at all.” Consequently, revenue from a license of drug compounds and formulas that represents a
distinct performance obligation would generally represent a right to use an entity’s IP and would be recognized at the point in time when control of the license is transferred to the customer. However, ASC 606-10-55-58C states the following:

Notwithstanding paragraphs 606-10-55-58A through 55-58B, revenue cannot be recognized from a license of intellectual property before both:

a. An entity provides (or otherwise makes available) a copy of the intellectual property to the customer.

b. The beginning of the period during which the customer is able to use and benefit from its right to access or its right to use the intellectual property. That is, an entity would not recognize revenue before the beginning of the license period even if the entity provides (or otherwise makes available) a copy of the intellectual property before the start of the license period or the customer has a copy of the intellectual property from another transaction. For example, an entity would recognize revenue from a license renewal no earlier than the beginning of the renewal period.

**Connecting the Dots**

Because revenue from customer renewals of licenses of IP cannot be recognized before both of the conditions in ASC 606-10-55-58C are met, revenue from a renewal of a right-to-use license is not recognized until the beginning of the renewal period, rather than when the parties agree to the renewal. This requirement may result in a change in practice for life sciences entities that historically have recognized fees on renewal rather than at the beginning of the renewal term.

**Q&A 2-41 Considerations for Determining Whether a License Is Predominant**

Under the sales- or usage-based royalty exception to the new revenue standard’s general rule requiring an entity to include variable consideration in the transaction price, if an entity is entitled to consideration in the form of a sales- or usage-based royalty, revenue is not recognized until (1) the underlying sales or usage has occurred and (2) the related performance obligation has been satisfied (or partially satisfied). That is, an entity is not required to estimate the amount of a sales- or usage-based royalty at contract inception; rather, revenue would be recognized when (or as) the subsequent sales or usage occurs (assuming that the associated performance obligation has been satisfied or partially satisfied).

As explained in ASC 606-10-55-65A, the sales- or usage-based royalty exception applies “when the royalty relates only to a license of intellectual property or when a license of intellectual property is the predominant item to which the royalty relates (for example, the license of intellectual property may be the predominant item to which the royalty relates when the entity has a reasonable expectation that the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates)” (emphasis added).

In the life sciences industry, licenses are often included with R&D services, manufacturing services, or both, with consideration in the form of a sales-based royalty. When the license and the services do not qualify as separate performance obligations, an entity will need to use significant judgment to assess whether the IP license is “the predominant item to which the royalty relates.”

**Question**

What factors should a life sciences entity consider in determining whether a license is predominant and therefore subject to the sales- or usage-based royalty exception?
Answer
The new revenue standard does not define “predominant.” However, ASC 606-10-55-65A notes that the license may be predominant “when the entity has a reasonable expectation that the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates.” Consequently, life sciences entities should consider the customer’s perspective of value and the relative importance and value of the promised goods or services. For example, in a combined license and R&D arrangement, an entity might consider the remaining clinical trial studies that need to be completed and the expected size of the market upon approval. Since different interpretations may arise in practice and the consequences of these differences could be significant to the timing of revenue recognition, entities are encouraged to contemporaneously document the basis for their conclusion on whether the license, rather than the other services, is predominant.

Q&A 2-42  Applicability of the Sales- or Usage-Based Royalty Exception to Sales-Based Milestones, Development-Based Milestones, or Guaranteed Minimum Royalties

Question
Is the sales- or usage-based royalty exception applicable to sales-based milestones, development-based milestones, or guaranteed minimum royalties?

Answer
The sales- or usage-based royalty exception would apply to sales-based milestones as the payment becomes due on the basis of the subsequent sales to the customer. However, the exception cannot be applied to development-based milestone payments because these payments are not contingent on the sales to or usage by the customer. In addition, the exception cannot be applied to guaranteed minimum royalties because those payments are essentially fixed consideration. However, the exception would apply to any variable consideration that exceeds the fixed (guaranteed minimum) portion.

Q&A 2-43  Application of the Sales- or Usage-Based Royalty Exception to a Variable Royalty Arrangement With Declining Royalties

An entity may enter into a contract with a customer in which the parties agree to a variable royalty arrangement with declining royalties. Consider the example below.

Example
An entity enters into a contract to provide a customer with a noncancelable license to the entity’s IP. The entity determines that the license is a right-to-use license (i.e., a license for which revenue is recognized at a point in time) for a three-year period. The customer’s estimated sales are expected to be approximately equal for each of the three years under license. For the use of the IP, the agreement requires the customer to pay the entity a royalty of 10 percent of the customer’s sales in year 1, 8 percent of the customer’s sales in year 2, and 6 percent of the customer’s sales in year 3.

Question
In the example above, should the entity account for the royalty payments by using the general model, which requires estimates of variable consideration?
**Answer**

No. The entity should account for the royalty payments in a manner consistent with the legal form of the arrangement and in accordance with the exception to the variable consideration guidance for licenses of IP that include a sales- or usage-based royalty. Consequently, the entity would include the royalties in the transaction price on the basis of the applicable contractual rate and the customer's sales in each year and then, in accordance with ASC 606-10-55-65, recognize revenue at the later of when (1) the “subsequent sale or usage occurs” or (2) the “performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).”

2.11 Presentation

2.11.1 Contract Assets and Contract Liabilities

<table>
<thead>
<tr>
<th>ASC 606-10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>45-1</strong> When either party to a contract has performed, an entity shall present the contract in the statement of financial position as a contract asset or a contract liability, depending on the relationship between the entity's performance and the customer's payment. An entity shall present any unconditional rights to consideration separately as a receivable.</td>
</tr>
<tr>
<td><strong>45-2</strong> If a customer pays consideration, or an entity has a right to an amount of consideration that is unconditional (that is, a receivable), before the entity transfers a good or service to the customer, the entity shall present the contract as a contract liability when the payment is made or the payment is due (whichever is earlier). A contract liability is an entity's obligation to transfer goods or services to a customer for which the entity has received consideration (or an amount of consideration is due) from the customer.</td>
</tr>
<tr>
<td><strong>45-3</strong> If an entity performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, the entity shall present the contract as a contract asset, excluding any amounts presented as a receivable. A contract asset is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer. An entity shall assess a contract asset for impairment (credit losses) in accordance with Topic 310 on receivables (Subtopic 326-20 on financial instruments measured at amortized cost). An impairment (A credit loss) of a contract asset shall be measured, presented, and disclosed in accordance with Topic 310 (Subtopic 326-20) (see also paragraph 606-10-50-4(b)).</td>
</tr>
</tbody>
</table>

A contract with a customer creates legal rights and obligations. The rights under the contract will generally give rise to contract assets as the entity performs (or accounts receivable, if an unconditional right to consideration exists); and contract liabilities are created when consideration is received in advance of performance. Each reporting period, an entity is required to assess its financial position related to its contracts with customers. Depending on the extent to which an entity has performed and the amount of consideration received (or receivable) by the entity under a contract, the entity could record a contract asset or a contract liability.

Receivables should be recorded separately from contract assets since only the passage of time is required before consideration is due. That is, receivables are only subject to credit risk. In contrast, contract assets are subject to more than just credit risk (i.e., they are also subject to performance risk). For example, a contract asset would exist when an entity has a contract with a customer for which revenue has been recognized (i.e., goods or services have been transferred to the customer) but customer payment is contingent on a future event (i.e., satisfaction of additional performance obligations or other events). As discussed in paragraph BC323 of ASU 2014-09, the FASB and IASB believed that making a distinction between contract assets and receivables was important to financial statement users.

Pending content effective upon adoption of ASU 2016-13 (in braces).
ASC 606-10-45-5 addresses the use of alternative descriptions for contract assets and contract liabilities as follows:

<table>
<thead>
<tr>
<th>ASC 606-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-5 This guidance uses the terms contract asset and contract liability but does not prohibit an entity from using alternative descriptions in the statement of financial position for those items. If an entity uses an alternative description for a contract asset, the entity shall provide sufficient information for a user of the financial statements to distinguish between receivables and contract assets.</td>
</tr>
</tbody>
</table>

Paragraph BC321 of ASU 2014-09 notes the FASB's and IASB's observation that “some industries have historically used different labels to describe contract assets and contract liabilities or may recognize them in more than one line item either in the financial statements or in the notes.” The ASU does not prohibit an entity from using alternative terms or from using additional line items to present the assets and liabilities, but it requires an entity to provide appropriate disclosures that adequately describe the assets and liabilities.

Terms that are commonly used in practice to describe contract assets and contract liabilities include, but are not limited to, the following:

- **Contract assets** — Unbilled receivables, progress payments to be billed.
- **Contract liabilities** — Deferred revenue, unearned revenue.

**Connecting the Dots**

In the life sciences industry, CROs typically enter into long-term contracts with their customers to perform clinical trial management services. Revenue from these services is generally recognized over time. It is not uncommon for a CRO to perform under a contract in such a way that performance to date exceeds the amounts of consideration received (or receivable) and the CRO records a contract asset. For example, a CRO may have to meet certain contractual milestones, such as patient enrollment metrics or investigator site approval, before having a right to bill.

There is diversity in practice on how CROs present these amounts in the statement of financial position and the descriptions used for these amounts. ASU 2014-09 indicates that an entity should provide sufficient information for a user of the financial statements to distinguish between receivables and contract assets. One presentation option is to present accounts receivable, unbilled services (i.e., services for which the right to bill is contingent solely on the passage of time), and contract assets (contingent on a future event) as individual line items in the statement of financial position. Alternatively, certain CROs may present one line item in the statement of financial position for amounts that are contingent solely on the passage of time (e.g., accounts receivable and unbilled services) and another line item for amounts that are contingent on events other than the passage of time (e.g., contract assets), then disclose the composition of the balance in the financial statement footnotes. Either approach is acceptable provided that the disclosures are sufficiently clear to enable a financial statement user to understand the nature and composition of the entity’s accounts receivable and contract assets, including whether contract assets are conditioned on something other than the passage of time.
2.11.2 Government Grants

In the life sciences industry, it is common for an entity that is not an NFP to receive government grants in support of R&D activities of the entity that are not associated with a customer/vendor relationship and are therefore outside the scope of the new revenue standard. Because there is no authoritative guidance under U.S. GAAP on accounting for government grants received, life sciences entities have considered applying sources of nonauthoritative accounting guidance and literature by analogy when accounting for government grants. With respect to recognition, measurement, and income statement presentation, some entities may have adopted an accounting policy of applying IAS 20 by analogy; depending on the nature of the grant, such a policy may have resulted in accounting for a particular grant as (1) a reduction of an asset, (2) an offset to an operating expense, or (3) income. Given the lack of authoritative U.S. GAAP related to the accounting for government grants, it is critical for an entity to disclose its accounting policy for government grants when such amounts are material to the entity’s financial statements. See Section 13.1 for more information, including a discussion of recent standard-setting activity related to disclosures about government assistance.

2.11.3 Gross Versus Net Presentation of Revenue

As noted in Section 2.2.1, ASC 808 requires that each collaboration participant report costs incurred and revenue generated from transactions with third parties in its income statement in accordance with the principal-versus-agent guidance in ASC 606-10-55-36 through 55-40. The entity that is identified as the principal in a transaction will recognize revenue based on the gross amount of consideration to which the entity expects to be entitled in exchange for the specified good or service transferred. In contrast, the entity that is identified as the agent in a transaction will recognize revenue based on the net amount of consideration to which the entity expects to be entitled in exchange for the specified good or service transferred.

Application of the principal-versus-agent guidance that affects whether a life sciences entity recognizes revenue based on gross or net amounts is not limited to collaborative arrangements. For example, business development transactions in the life sciences industry frequently involve transition services arrangements in which the seller performs certain transition services for the buyer (e.g., distribution, billing, and collections) while marketing authorizations are obtained by the buyer to sell pharmaceutical product in the jurisdiction. To determine whether the buyer should report revenues on a gross or a net basis during the transition period, the buyer should assess whether the nature of the seller’s promise to the customer is a performance obligation to provide the specified goods or services itself (i.e., the seller is a principal) or to arrange for those goods or services to be provided by the buyer (i.e., the seller is an agent), as indicated in ASC 606-10-55-36.

In accordance with ASC 606-10-55-36A, an entity should determine the nature of its promise by identifying the specified goods or services to be provided to the customer and assessing whether it controls each specified good or service before that good or service is transferred to the customer. When making this determination under the new revenue standard, the entity may be required to use significant judgment, as it was required to do under legacy U.S. GAAP. Legacy guidance relied on a risks-and-rewards model for determining how and when to recognize revenue, as it did for determining whether an entity is a principal or an agent in a transaction. In contrast, the new revenue standard is focused on recognizing revenue as an entity transfers control of a good or service to a customer.
2.12 Disclosure Requirements

As discussed in paragraph BC327 of ASU 2014-09, some of the main criticisms of the prior revenue guidance from regulators and users of the financial statements were related to disclosure requirements. Many entities’ disclosures contained boilerplate language that, broadly speaking, regulators and users found to be inadequate and lacking in cohesion with other disclosures, thus making it difficult for users to understand entities’ revenues, judgments related to revenue, and how revenue was related to an entity’s overall financial position. In addition, while disclosure has been a focus of the FASB and SEC in recent years, that focus has been primarily related to disclosure overload and extensive disclosures required on topics such as pensions, stock compensation, fair value, and income taxes. In response to stakeholder feedback, the FASB has aimed to make disclosures more effective, better coordinated, and less redundant. This sharper focus will most likely result in reduced disclosures in many cases. Although this has been an overall focus of the FASB and SEC, the lack of disclosure on revenue was highlighted as a key area for improvement during the development of the new revenue standard.

As a result, one of the goals of the FASB and IASB in the revenue project was to provide financial statement users with more useful information through improved disclosures. ASC 606-10-50-1 outlines the objective of the new revenue standard’s disclosure requirements as follows:

<table>
<thead>
<tr>
<th>ASC 606-10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>50-1</strong> The objective of the disclosure requirements in this Topic is for an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. To achieve that objective, an entity shall disclose qualitative and quantitative information about all of the following:</td>
</tr>
<tr>
<td>a. Its contracts with customers (see paragraphs 606-10-50-4 through 50-16)</td>
</tr>
<tr>
<td>b. The significant judgments, and changes in the judgments, made in applying the guidance in this Topic to those contracts (see paragraphs 606-10-50-17 through 50-21)</td>
</tr>
<tr>
<td>c. Any assets recognized from the costs to obtain or fulfill a contract with a customer in accordance with paragraph 340-40-25-1 or 340-40-25-5 (see paragraphs 340-40-50-1 through 50-6).</td>
</tr>
</tbody>
</table>

Some of the more common issues that life sciences entities have addressed when considering the disclosure requirements of the new revenue standard are discussed below.

2.12.1 Level of Aggregation or Disaggregation

To comply with the “entity-wide” disclosure requirements of ASC 280, many life sciences companies already disclose revenues from products for major medical treatments, revenues from different types of services (e.g., clinical development services vs. commercial services), revenues attributed to the entity’s home country and foreign countries, and the individual customers (e.g., wholesalers) whose purchases constitute 10 percent or more of the entity’s revenues. These disclosures have not changed for many life sciences companies upon the adoption of the new revenue standard, but entities are encouraged to document their consideration of the disaggregation categories outlined in ASC 606.
2.12.2 Satisfied Performance Obligations

ASC 606 requires disclosure of the amount of revenue recognized in the current period that is related to amounts allocated to performance obligations that were satisfied (or partially satisfied) in previous periods (e.g., because of changes in the variable consideration constraint). For example, development- or approval-based milestone payments related to the delivery of a functional license of IP may have been fully constrained because of the uncertainty of achieving the milestones. Once the milestone payments are no longer constrained, an entity would be required to disclose the milestone payments recognized in the current period that are related to amounts allocated to performance obligations that were satisfied (or partially satisfied) in previous periods.

2.12.3 Gross-to-Net Disclosures

Many pharmaceutical companies currently disclose a rollforward of gross-to-net balance sheet reserves in MD&A. Some registrants also disclose a reconciliation of gross and net sales as reported in the income statement. Some life sciences companies have considered including these types of disclosures in the footnotes to the financial statements to meet certain variable consideration disclosure requirements of the new revenue standard, such as those related to disclosure of changes in estimates associated with the transaction price and estimates associated with the variable consideration.

2.12.4 SEC Comment Letter Themes Related to Disclosures

At the 13th Annual Life Sciences Accounting & Reporting Congress, held on March 21, 2017, SEC Chief Accountant Wesley Bricker stated that because no two arrangements are identical, preparers should go beyond benchmarking to their peers’ accounting policies to fully understand each underlying transaction so that they can apply the principles of ASC 606. Further, he noted that preparers need to identify the pertinent facts and related judgments that must be disclosed under the new revenue standard.

In a manner consistent with Mr. Bricker’s comments, the SEC staff appears to be focusing on disclosures of significant judgments. As of September 2018, it appeared that more than 35 percent of the publicly available ASC 606 SEC staff comments were related to disclosures of significant judgments. These comments can be broken into the following four broad categories (1) identification of performance obligations, (2) determination of the transaction price, (3) allocation of the transaction price, and (4) identification of a measure of progress.

See Deloitte’s September 26, 2018, Heads Up for more information about the key themes noted in our review of approximately 100 SEC staff comments issued as of September 2018 on the accounting and disclosure requirements of ASC 606, as well as examples of those comments.

2.12.5 Elective Relief for Nonpublic Entities

The Background Information and Basis for Conclusions of ASU 2014-09 explains that one of the goals of ASC 606 is to improve the revenue disclosure guidance under U.S. GAAP. As a result of the disclosure requirements in ASC 606, financial statement users will have better information to help them make financial decisions. However, when the FASB was developing the new standard, it received feedback from nonpublic entities related to (1) the increased costs that nonpublic entities would incur to meet the improved disclosure requirements and (2) questions about why nonpublic entities should be required to provide the same level of disclosure as PBEs given that users of nonpublic-entity financial statements, typically debt holders, have greater access to management. The FASB considered the costs and benefits of its disclosure package and decided to provide various relief to nonpublic entities.
The table below summarizes the disclosure requirements of ASU 2014-09 that a nonpublic entity may elect not to apply.

<table>
<thead>
<tr>
<th>Category</th>
<th>Disclosure Requirements</th>
<th>Election Available to Nonpublic Entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disaggregation of revenue</td>
<td>Disaggregate revenue into categories that depict how revenue and cash flows are affected by economic factors.</td>
<td>Yes⁴</td>
</tr>
<tr>
<td></td>
<td>Sufficient information to understand the relationship between disaggregated revenue and each disclosed segment’s revenue information.</td>
<td>Yes</td>
</tr>
<tr>
<td>Contract balances</td>
<td>Opening and closing balances (receivable, contract assets, and contract liabilities).</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Amount of revenue recognized from beginning contract liability balance.</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Explanation of significant changes in contract balances (using qualitative and quantitative information).</td>
<td>Yes</td>
</tr>
<tr>
<td>Performance obligations (including remaining performance obligations)</td>
<td>Qualitative information about (1) when performance obligations are typically satisfied, (2) significant payment terms, (3) the nature of goods or services promised, (4) obligations for returns or refunds, and (5) warranties.</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Amount of revenue recognized from performance obligations satisfied in prior periods (e.g., changes in transaction price estimates).</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Transaction price allocated to the remaining performance obligations:</td>
<td>Yes⁴</td>
</tr>
<tr>
<td></td>
<td>• Disclosure of quantitative amounts.</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>• Quantitative or qualitative explanation of when remaining performance obligation amounts will be recognized as revenue.</td>
<td>Yes⁴</td>
</tr>
</tbody>
</table>

⁴ At a minimum, an entity must disclose revenue that is disaggregated in accordance with the timing of transfer of goods or services (e.g., goods transferred at a point in time and services transferred over time).
See Chapters 14 and 16 of Deloitte’s Revenue Roadmap for more information about the new revenue standard’s disclosure requirements, including those that nonpublic entities may elect not to apply. In addition, see Deloitte’s April 11, 2018, Heads Up for more information about what private companies should know about the new revenue standard.

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5 The election available to nonpublic entities applies only to the requirement to disclose information about why the methods used to recognize revenue over time provide a faithful depiction of the transfer of goods or services to a customer. Nonpublic entities are still required to disclose the information about the methods used to recognize revenue over time in accordance with ASC 606-10-50-18(a).

6 This includes the methods, inputs, and assumptions used in an entity’s assessment.
2.13 Effective Date and Transition

2.13.1 Effective Date
For PBEs as well as certain NFPs and employee benefit plans, the new revenue standard became effective for annual reporting periods beginning after December 15, 2017. For all other entities, the standard is effective for annual reporting periods beginning after December 15, 2018. Early adoption is permitted as applicable.

2.13.2 Transition Methods
Entities that have not yet adopted the new revenue standard should keep in mind that they have the option of using either a full retrospective or modified retrospective method to adopt the guidance in the new revenue standard:

- **Full retrospective application** — Retrospective application would take into account the requirements of ASC 250 (with certain practical expedients).
- **Modified retrospective application** — ASC 606-10-65-1(h) states that under the modified retrospective method, an entity recognizes “the cumulative effect of initially applying [ASU 2014-09] as an adjustment to the opening balance of retained earnings . . . of the annual reporting period that includes the date of initial application” (revenue in periods presented in the financial statements before that date is reported under guidance in effect before the change). When using this method, an entity applies the guidance in the ASU (as amended by ASU 2016-12) to either of the following:
  - Incomplete contracts (i.e., those contracts for which all (or substantially all) of the revenue has not been recognized in accordance with prior revenue guidance) as of the date of initial application.
  - All contracts as of, and new contracts after, the date of initial application.

Entities should carefully evaluate the respective advantages and disadvantages of each of the transition methods before selecting their method of adopting the new revenue standard. The transparent trend information provided under the full retrospective method may be most effective for entities that expect to experience a significant change. Also, entities that have significant deferred revenue balances may prefer a full retrospective method to ensure that such revenue is not “lost” from operations by its recognition as a cumulative-effect adjustment to retained earnings. However, the full retrospective method could require significant effort since the adjustments to prior reported results will change not only the revenue recognized but also the other “direct effects of a change” as defined in ASC 250.

Q&A 2-44 Special Considerations for Determining Which Transition Approach to Use

**Question**
In the evaluation of the transition approach to use, are there any considerations that may be unique to life sciences entities?
Answer

As previously noted, collaborative arrangements are common in the life sciences industry, and many entities apply revenue literature directly or by analogy in the accounting for these arrangements. As life sciences entities with such collaborative arrangements evaluate which transition approach to use, they may need to consider the transition approach elected by their collaboration partners to ensure that the necessary information will be available to restate prior periods (if the full retrospective approach is used) or determine the cumulative-effect adjustment (if the modified retrospective approach is used).

In addition, life sciences entities may need to consider working with their collaboration partners to ensure that the parties are appropriately compensated for any changes in historical profit arising from differences in the amounts of revenue and costs from those previously reported. For any such changes in contractual cash flows that arise from these differences, entities are reminded that ASC 250-10-45-8 requires such “indirect effects” of changes in accounting principle to be reported in the period in which the accounting change is made (i.e., indirect effects are not included in the retrospective application).
Chapter 3 — Research and Development

3.1 Introduction

New product development in the life sciences industry can be both time-consuming and costly. As markets have evolved over recent years, profitability has been constrained as a result of pricing challenges and scrutiny, rising materials and development costs, increased difficulty in sourcing innovative solutions, and more stringent government regulations.

In response to these pressures, companies are focusing on specialized R&D models that require enhanced capabilities to promote greater R&D efficiency. Life sciences companies are working to reduce research costs by outsourcing research to external partners, making acquisitions of promising products in late-stage development, enhancing drug discovery and development platforms, and optimizing product approval timelines. In addition, companies are entering into various funding relationships to reduce the burden of R&D expense through collaborations, licensing arrangements, partnerships, and other alliances.

As these R&D arrangements become more complex, so do the accounting requirements and considerations that entities must evaluate. Companies need to consider the substance of the R&D relationship, risks associated with such arrangements, and related deliverables to determine the appropriate accounting models and literature that will apply.

In Section 3.2 below, we explore various R&D issues that many life sciences companies encounter, the related accounting guidance, and recent SEC observations regarding registrants’ accounting for and disclosure of R&D costs.

3.2 Industry Issues

3.2.1 R&D Funding Arrangements

The need for new sources of capital in the life sciences industry has led to innovative R&D funding arrangements with diverse terms and conditions. In these arrangements, passive third-party investors often provide funds to offset the cost of R&D programs in exchange for milestone payments or other forms of consideration (typically sales-based royalties) that are contingent on the successful completion of such R&D programs and the related approval for the compound(s) being developed. Typically, life sciences companies retain all IP rights to any compounds resulting from the R&D efforts, and the investor does not receive repayment or any other forms of consideration if the compound or compounds subject to the R&D arrangement are not successfully developed and commercialized.
Q&A 3-1 Considerations Relevant to a Life Sciences Company’s Accounting for an R&D Funding Arrangement

Question
What factors should a life sciences company that receives R&D funding consider when accounting for an R&D funding arrangement?

Answer
To determine the appropriate accounting treatment, the company should first consider whether the arrangement includes elements that need to be accounted for under the guidance on derivatives in ASC 815.

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

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.

Depending on the terms of the transaction, an R&D funding arrangement may contain an underlying (e.g., the underlying net sales, which are dependent on regulatory approval) and a payment provision (e.g., sales-based royalty payments to the investor, which are based on future levels of net sales of the compound being developed) without an initial net investment (i.e., the investor may only be required to fund the R&D costs as such costs are incurred). In addition, R&D funding arrangements often contain the characteristic of explicit net settlement since they are settled in cash.

If the life sciences company determines that its R&D funding arrangement meets the definition of a derivative instrument, it should assess whether the arrangement represents a contract that would meet any of the scope exceptions in ASC 815. For example, in certain transactions, the life sciences company is only required to make royalty payments to the investor if the compound is approved and net sales occur. In these circumstances, the scope exception described in
ASC 815-10-15-13(e) and ASC 815-10-15-59(d) for certain contracts that are not traded on an exchange may apply. ASC 815-10-15-13(e) and ASC 815-10-15-59(d) state the following:

**Instruments Not Within Scope**

15-13 Notwithstanding the conditions in paragraphs 815-10-15-83 through 15-139, the following contracts are not subject to the requirements of this Subtopic if specified criteria are met: . . .

e. Certain contracts that are not traded on an exchange

**Certain Contracts That Are Not Traded on an Exchange**

15-59 Contracts that are not exchange-traded are not subject to the requirements of this Subtopic if the underlying on which the settlement is based is any one of the following . . .

d. Specified volumes of sales or service revenues of one of the parties to the contract. (This scope exception applies to contracts with settlements based on the volume of items sold or services rendered, for example, royalty agreements. This scope exception does not apply to contracts based on changes in sales or revenues due to changes in market prices.) [Emphasis added]

If the life sciences company determines that its R&D funding arrangement does not include elements that need to be accounted for under the guidance on derivatives in ASC 815, it should consider, among other things, the risks associated with the R&D program being funded as well as the deliverable(s) (i.e., license rights to IP subject to the R&D program) to be provided to the funding party. Such factors may inform the company’s decision about which accounting literature to consider next, particularly if the company concludes that the arrangement is a contract to perform services that should be accounted for under ASC 606.

A critical assessment is whether the life sciences company has an obligation to repay the funding party or is under a contract to perform R&D services. If a determination is made at the onset of the arrangement that successful completion of the R&D is probable, it may be more appropriate to treat the arrangement as the sale of future revenues under ASC 470-10-25 than as an R&D funding arrangement under ASC 730-20. The application of ASC 470-10-25 would generally result in debt classification for the funding because of the life sciences company's continuing involvement with the associated R&D.

If a conclusion is reached that ASC 470-10-25 does not apply, the life sciences company should next evaluate ASC 730-20 to determine whether the arrangement represents an obligation to repay the funding party or a contract to perform services. ASC 730-20-25-3 notes that “[i]f the entity is obligated to repay any of the funds provided by the other parties regardless of the outcome of the research and development, the entity shall estimate and recognize that liability. This requirement applies whether the entity may settle the liability by paying cash, by issuing securities, or by some other means.”

ASC 730-20-25-4 cautions preparers that to support a conclusion that a liability does not exist, “the transfer of the financial risk involved with research and development from the entity to the other parties must be substantive and genuine.” The provision also states that “[t]o the extent that the entity is committed to repay any of the funds provided by the other parties regardless of the outcome of the research and development, all or part of the risk has not been transferred.”
In addition, ASC 730-20-25-4 lists the following examples of circumstances in which risk has not been transferred:

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

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

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

**Connecting the Dots**

Companies in the life sciences industry typically assign probability of technical and regulatory success (PTRS) rates to development-stage compounds on the basis of estimates of the likelihood that such compounds eventually will be approved by the FDA or other regulatory organizations. Because companies often use PTRS rates to determine resource and capital allocation strategies, it is often important for companies to consider the PTRS rate for a respective compound in evaluating whether successful completion of the R&D is probable at the onset of the arrangement. However, there is no “bright line” PTRS rate for determining whether successful completion of the R&D is considered probable. Therefore, companies should consider all facts and circumstances in making such a determination.

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

- **Multiple products (the “basket approach”)** — An investor’s risk is reduced by having an increased number of covered products as well as by other factors (e.g., number of products, stage of development of each, payment mechanisms).
- **Repayment upon achievement of clinical development milestones** — An investor’s risk is reduced if repayment is triggered upon achievement of an event before regulatory approval (e.g., upon “proof of concept” demonstrating that the drug may be efficacious).
• **Substitution rights** — An investor's risk is reduced by the right to replace a failed molecule or project in the R&D arrangement with one or more other molecules or projects that still have the potential to be commercialized.

• **Royalty rates based on commercialization sequence** — An investor's risk is reduced by assigning a royalty rate (typically the highest) to the first successful outcome within a portfolio of products, with lower rates assigned to each successive outcome that has no direct economic correlation to product market potential or probability of success.

• **Rights to unrelated revenue streams** — An investor's risk is reduced by incorporating rights to cash flows from an unrelated revenue stream, such as a royalty on a separate and distinct product for which the investor did not fund the related R&D. If cash flows associated with an unrelated revenue stream (i.e., milestone or royalty payments related to sales of developed products unrelated to the compounds that were subject to the R&D funding arrangement) are included in accordance with the terms of the arrangement, the guidance in ASC 470-10-25 on sales of future revenue streams should be considered.

**Connecting the Dots**

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

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

If an entity concludes that substantive and genuine risk transfer has occurred, questions may then arise about the appropriate income statement classification of the funding received from the investor since ASC 730-20 does not provide guidance on the income statement classification for funding accounted for as an obligation to perform contractual services for others. ASC 808 provides guidance on classification of payments for transactions between collaboration partners, and ASC 606 provides guidance on gross versus net presentation of revenue.

We believe that entities should consider the nature of their ongoing, major, or central operations in determining the appropriate income statement classification. If an entity's arrangement is consistent with the entity's central operations (i.e., the entity regularly performs R&D on behalf of others who are generally viewed as customers), classification as revenue may be appropriate. If the arrangement is inconsistent with the entity's central operations, classification as contra-R&D expense or other income may be more appropriate.
In determining whether to classify funding from an investor as contra-R&D expense or as other income, a life sciences entity might consider the extent of involvement of the counterparty in the R&D effort. For example, if the counterparty is actively involved through participation on a joint steering committee or in the performance of certain R&D activities, classification as contra-R&D expense may be appropriate. This classification may be further supported by analogy to ASC 410-30-45-4, which states that “[c]redits arising from recoveries of environmental losses from other parties shall be reflected in the same income statement line.” That is, the life sciences entity might conclude that the funding to be received from the investor (i.e., the “credits”) should be reflected in the same income statement line item as the expenses to which the funding is related. Alternatively, if the counterparty is only passively involved, the entity might conclude that classification as other income may be more appropriate.

### 3.2.1.1 R&D Funding Arrangements Involving New Legal Entities

#### Q&A 3-2 Considerations Relevant to a Pharmaceutical Company’s Accounting for an R&D Funding Arrangement That Involves the Formation of a New Legal Entity

**Question**

What considerations should a pharmaceutical company take into account when an R&D funding arrangement involves the formation of a new legal entity?

**Answer**

Historically, it was not common for separate legal entities to be created to facilitate R&D funding arrangements; however, some recent arrangements have included the formation of a new legal entity. Typically, the new legal entity is 100 percent owned by a financial investor, and the pharmaceutical company may be involved through participation on a committee (e.g., steering committee) or by performing R&D services through an outsourcing arrangement. The pharmaceutical company may also have the right or option to reacquire the rights to the compound(s) at a later date.

When an R&D arrangement involves the formation of a new legal entity, the pharmaceutical company must also consider the consolidation guidance in ASC 810 to determine whether it is required to consolidate the legal entity. Typically, the R&D legal entity is a variable interest entity (VIE) because (1) the power to direct the activities of the legal entity is not possessed by the equity investors or (2) the pharmaceutical company’s right or option to reacquire the rights to the compound effectively limits the returns that can be received by the financial investor. In these situations, the evaluation should include consideration of whether the pharmaceutical company has the power to direct the activities most significant to the legal entity’s economic performance. For example, the power to make decisions related to the design or operation of clinical studies may indicate that the pharmaceutical company has power over the entity’s most significant activities and that therefore, consolidation may be required.

The power to make the most significant decisions could reside with different parties depending on a product candidate’s stage of development and should be considered in the consolidation analysis. Further, careful consideration should also be given when either the decisions of the financial investor(s) are passive or predetermined or the pharmaceutical company has a fixed-price call option to acquire the legal entity since these types of circumstances could suggest that (1) the financial investors lack the characteristics of a controlling financial interest and (2) the pharmaceutical company controls and should consolidate the legal entity.
If a pharmaceutical company concludes that consolidation of an R&D entity is required, the percentage of equity not owned by the pharmaceutical company would be presented as a noncontrolling interest (which could be 100 percent of the legal entity’s equity). Further, it is important to determine whether the financial investor’s equity investment has all of the characteristics of equity. If it does not, temporary equity or liability classification of the noncontrolling interest may be required depending on the facts and circumstances.

3.2.1.2 R&D Arrangements Involving a Sponsor of a New Company

For arrangements involving the creation of a new legal entity, a reporting entity should first determine whether the new legal entity meets the definition of a VIE and, if so, whether the reporting entity should consolidate the VIE (as discussed above). If the new legal entity is not a VIE, or if the new legal entity is a VIE but is not consolidated by the reporting entity, additional consideration of the guidance in ASC 810-30 may be required.

Q&A 3-3 Whether an R&D Arrangement in Which a Sponsor Capitalizes a New Company Should Be Accounted for Under ASC 810-30

ASC 810-30-55 contains an illustrative example that discusses R&D arrangements in which a sponsor capitalizes a new entity ("Newco") with cash and rights to certain technology developed by the sponsor in exchange for Class A and Class B common stock in Newco. The Class B common shares convey essentially no financial interest to the sponsor and, other than certain blocking rights, provide the sponsor essentially no voting rights. The sponsor subsequently distributes the Class A common stock to its shareholders subject to a purchase option held by the sponsor. The sponsor then receives funds from Newco to perform R&D activities.

ASC 810-30-25-3 states that the sponsor of an R&D arrangement should account for the arrangement as follows:

a. Reclassify the cash contributed to the new entity as restricted cash at the time of distribution of the new entity’s Class A common stock.

b. Recognize research and development expense as the research and development activities are performed.

c. Account for the distribution of the new entity’s Class A common stock as a dividend to common stockholders of the sponsor.

However, this accounting applies narrowly to the fact pattern outlined in ASC 810-30-55. For an alternative fact pattern, consider the scenario in the example below.

Example

An employee of Entity A announces his intention to leave A and start a new technology company. He and three other individuals unrelated to A subsequently incorporate the new company, Entity B. Entity A agrees to effectively act as venture capitalist for B. The founders of B contribute nominal consideration to their start-up venture in exchange for B common stock, and A contributes $10 million to the venture in exchange for B preferred stock.

The terms of the agreement between A and B stipulate that while both parties would agree on the plan for developing a new technology, B would perform the development efforts at its expense and would have to obtain approval from A before subcontracting any of its obligations. After delivery of the technology to A, B has the right to put to A, and A has the right to call from B, all outstanding common shares of B. The terms of the put and call are identical and set fixed prices for the technology on certain dates, with the put and call terminating if the technology is not delivered by the deadline established in the agreement.
**Question**

Should A account for its investment in B by applying the guidance in ASC 810-30?

**Answer**

No. ASC 810-30 specifies the type of arrangement to which it applies. The scenario in this Q&A differs from the example in ASC 810-30-55 in the following key respects:

- The formation of the new company is not completed through capitalization of a new entity and a subsequent spin-off.
- The R&D work is completed by the new company and not by the sponsor.
- The put and call are exercisable only if the product is delivered.
- The new company’s operations, except for subcontracting, are not subject to the approval of the sponsor.

**Connecting the Dots**

In September 2017, the FASB issued a proposed ASU that would reorganize the consolidation guidance in ASC 810 by creating a new Codification topic, ASC 812, with separate subtopics for the guidance on (1) the VIE model and (2) the voting interest entity model. Under the proposal, the guidance currently in ASC 810-30 would be superseded. For additional information on the proposed ASU, see Deloitte’s October 5, 2017, *Heads Up*.

In June 2018, the FASB met to discuss comment letter feedback on the proposed ASU and decided to continue its existing project on reorganizing the consolidation guidance in ASC 810.

### 3.2.2 R&D Cost Classification

R&D costs are pivotal to life sciences entities as they fuel the future pipeline. Entities can spend billions of dollars on R&D costs in hopes of developing and gaining approval for their next blockbuster drug. These costs are generally classified separately in the income statement and are often a focus of financial statement users since they may provide insight into the entity’s future revenues.

ASC 730-10-20 defines “research and development” as follows:

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<th><strong>ASC 730-10 — Glossary</strong></th>
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<tr>
<td><strong>Research and Development</strong></td>
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<tr>
<td>Research is planned search or critical investigation aimed at discovery of new knowledge with the hope that such knowledge will be useful in developing a new product or service (referred to as product) or a new process or technique (referred to as process) or in bringing about a significant improvement to an existing product or process.</td>
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<td>Development is the translation of research findings or other knowledge into a plan or design for a new product or process or for a significant improvement to an existing product or process whether intended for sale or use. It includes the conceptual formulation, design, and testing of product alternatives, construction of prototypes, and operation of pilot plants.</td>
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ASC 730-10-25-2 explains the elements of costs to be identified with R&D activities:

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<tr>
<td><strong>25-2</strong> Elements of costs shall be identified with research and development activities as follows . . . :</td>
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<tr>
<td>a. Materials, equipment, and facilities. The costs of materials (whether from the entity's normal inventory or acquired specially for research and development activities) and equipment or facilities that are acquired or constructed for research and development activities and that have alternative future uses (in research and development projects or otherwise) shall be capitalized as tangible assets when acquired or constructed. The cost of such materials consumed in research and development activities and the depreciation of such equipment or facilities used in those activities are research and development costs. However, the costs of materials, equipment, or facilities that are acquired or constructed for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are research and development costs at the time such costs are incurred. . . .</td>
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<tr>
<td>b. Personnel. Salaries, wages, and other related costs of personnel engaged in research and development activities shall be included in research and development costs.</td>
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<tr>
<td>c. Intangible assets purchased from others. The costs of intangible assets that are purchased from others for use in research and development activities and that have alternative future uses (in research and development projects or otherwise) shall be accounted for in accordance with Topic 350. The amortization of those intangible assets used in research and development activities is a research and development cost. However, the costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are research and development costs at the time such costs are incurred.</td>
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<tr>
<td>d. Contract services. The costs of services performed by others in connection with the research and development activities of an entity, including research and development conducted by others in behalf of the entity, shall be included in research and development costs.</td>
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<tr>
<td>e. Indirect costs. Research and development costs shall include a reasonable allocation of indirect costs. However, general and administrative costs that are not clearly related to research and development activities shall not be included as research and development costs.</td>
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**Connecting the Dots**

**Assets Acquired or Constructed for Use in R&D Activities**

A life sciences company may need to acquire facilities and equipment to contribute to the development of a product candidate currently proceeding through the stages of clinical development.

In a manner consistent with ASC 730-10-25-2(a) and (c), tangible assets that are acquired or constructed, and intangible assets that are acquired, for use in R&D activities in a transaction other than a business combination are capitalized only if they have alternative future uses. Otherwise, the costs for such assets are R&D costs at the time such costs are incurred and are charged to expense in accordance with ASC 730-10-25-1.
Paragraph 3.17 of the AICPA Accounting and Valuation Guide *Assets Acquired to Be Used in Research and Development Activities* (the “AICPA Guide”) discusses the determination of whether such assets have an alternative future use:

The [AICPA IPR&D Task Force (the “task force”)] believes that the determination of whether an alternative future use exists for an asset is based on specific facts and circumstances. However, for an acquired tangible asset to be used in R&D activities (for example, computer testing equipment used in an R&D department), the task force believes that there is a rebuttable presumption that such asset has an alternative future use because that asset generally has separate economic value (other than scrap or insignificant value) independent of the successful completion and commercialization of the IPR&D project. This presumption would be overcome, for example, if it were reasonably expected that the reporting entity will use that asset only in a specific IPR&D project that had commenced before the acquisition date.

To illustrate the application of this guidance, suppose that Company X acquires a phase III drug in an asset acquisition and separately purchases various equipment (e.g., tanks, mixers, centrifuges) to be used in connection with the development of the drug. Although X acquires the equipment to support a specific product candidate, the nature of the equipment is common to pharmaceutical preparation and may have economic value apart from the specific IPR&D project (i.e., the equipment could be sold in a secondary market for an amount other than scrap value). Consequently, it may be appropriate to capitalize the cost of the equipment.

Conversely, suppose that X acquires (or internally develops) certain medical testing equipment that is reasonably expected to be used only in a specific IPR&D project that does not have any further use or separate economic benefit to the company or others. In accordance with ASC 730-10-25-2(a), X would immediately expense the cost, less salvage value, of the medical testing equipment since there is no alternative future use.

**Costs of Services Performed by Others in Connection With R&D Activities**

Life sciences companies frequently enter into contract research arrangements with third parties to perform research on compounds under development. The payment terms under these arrangements may be based on defined milestones (e.g., upon delivery of the research services) rather than on time incurred.

In a manner consistent with ASC 730-10-25-2(d), the costs of services performed by others in connection with an entity’s R&D activities should be accounted for as R&D costs of the entity and should be expensed as the entity becomes contractually obligated for them. To properly expense the contract research costs under the arrangement, the entity may need to obtain periodic progress reports from the vendors on the level of services provided to date for which the entity is contractually obligated to pay. This is because the timing of payments would not necessarily indicate the entity’s contractual obligation to pay for services performed by the vendors at a particular point in time.
In addition, ASC 730-10-55-1 and 55-2 list examples of activities that are commonly included in, or excluded from, R&D activities:

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<tr>
<td><strong>Examples of Activities Typically Included in Research and Development</strong></td>
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<tr>
<td><strong>55-1</strong> The following activities typically would be considered research and development within the scope of this Topic (unless conducted for others under a contractual arrangement — see paragraph 730-10-15-4[a]):</td>
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<tr>
<td>a. Laboratory research aimed at discovery of new knowledge</td>
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<td>b. Searching for applications of new research findings or other knowledge</td>
</tr>
<tr>
<td>c. Conceptual formulation and design of possible product or process alternatives</td>
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<tr>
<td>d. Testing in search for or evaluation of product or process alternatives</td>
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<tr>
<td>e. Modification of the formulation or design of a product or process</td>
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<tr>
<td>f. Design, construction, and testing of preproduction prototypes and models</td>
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<td>g. Design of tools, jigs, molds, and dies involving new technology</td>
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<tr>
<td>h. Design, construction, and operation of a pilot plant that is not of a scale economically feasible to the entity for commercial production</td>
</tr>
<tr>
<td>i. Engineering activity required to advance the design of a product to the point that it meets specific functional and economic requirements and is ready for manufacture</td>
</tr>
<tr>
<td>j. Design and development of tools used to facilitate research and development or components of a product or process that are undergoing research and development activities.</td>
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| **Examples of Activities Typically Excluded From Research and Development** |
| **55-2** The following activities typically would not be considered research and development within the scope of this Topic: |
| a. Engineering follow-through in an early phase of commercial production |
| b. Quality control during commercial production including routine testing of products |
| c. Trouble-shooting in connection with break-downs during commercial production |
| d. Routine, ongoing efforts to refine, enrich, or otherwise improve upon the qualities of an existing product |
| e. Adaptation of an existing capability to a particular requirement or customer's need as part of a continuing commercial activity |
| f. Seasonal or other periodic design changes to existing products |
| g. Routine design of tools, jigs, molds, and dies |
| h. Activity, including design and construction engineering, related to the construction, relocation, rearrangement, or start-up of facilities or equipment other than the following: |
| 1. Pilot plants (see [h] in the preceding paragraph) |
| 2. Facilities or equipment whose sole use is for a particular research and development project (see paragraph 730-10-25-2[a]). |
| i. Legal work in connection with patent applications or litigation, and the sale or licensing of patents. |
Connecting the Dots
As noted in the above examples, legal work in connection with patent applications or litigation does not meet the definition of R&D. However, questions about whether an entity may capitalize costs related to such legal work sometimes arise. AICPA TPA 2260.03 provides the following guidance on patent defense costs:

*Inquiry* — A company is sued for patent infringement. Should the cost to defend the patent be capitalized or expensed?

*Reply* — The choice of capitalizing or expensing depends on the outcome of the lawsuit. FASB Concept No. 6, *Elements of Financial Statements — a replacement of FASB Concepts Statement No. 3* (incorporating an amendment of FASB Concepts Statement No. 2), paragraph 247 states “...the legal and other costs of successfully defending a patent from infringement are ‘deferred legal costs’ only in the sense that they are part of the cost of retaining and obtaining the future economic benefit of the patent.”

If defense of the patent lawsuit is successful, costs may be capitalized to the extent of an evident increase in the value of the patent. Legal costs which relate to an unsuccessful outcome should be expensed.

Accordingly, capitalization of patent defense costs is appropriate only when a successful patent defense is likely to occur and the value of the patent is expected to increase as a result. Often, defense of a patent maintains rather than increases the value of the patent, in which case defense costs should be expensed as incurred.

In addition, because of the uncertainty associated with the successful development of IP rights, legal costs incurred in connection with a patent application are generally expensed as incurred.

ASC 730-10-15-4(c) and (e) exclude from the scope of ASC 730 the “acquisition, development, or improvement of a process by an entity for use in its selling or administrative activities” and “[m]arket research or market testing activities,” respectively. Therefore, such transactions and activities should not be classified as R&D.

Determining the classification of certain costs may be straightforward when the costs align closely with the definition and examples of R&D in ASC 730. However, certain costs associated with some activities require more judgment since the activities can have characteristics of both R&D and selling and marketing. Costs associated with certain activities that might require further judgment for classification as R&D under ASC 730 include, but are not limited to, the following:

- **Phase IV studies** — Conducted after the drug or treatment has been marketed, these studies are frequently performed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

- **Investigator-initiated research (IIR)** — IIR projects are similar to phase IV studies but are conducted by third-party investigators with oversight provided by the entity. Both phase IV studies and IIR provide a framework for research to increase the understanding of diseases, disease management, or drug use and effects in various patient populations.
• **Grants** — Grants fund independent medical education programs that are intended to enhance the knowledge base of health care professionals and provide a forum for discussion of new data, information, and other knowledge that could generate ideas related to the development of other products.

• **Pharmacovigilance** — Entities incur pharmacovigilance costs to collect, analyze, and report safety data associated with the use of a drug. Information obtained through pharmacovigilance could lead to new knowledge that may result in the significant modification of existing products, modifications to the method of use for existing products, or the development of new products to curb adverse reactions in patient populations.

• **Medical science liaison (MSL)** — An MSL organization delivers clinical and scientific data and clinical education to key thought leaders, professional societies, and practitioners associated with an entity’s products and various disease states.

• **Risk evaluation and mitigation strategy (REMS)** — A REMS is a safety strategy that entities use to manage a known or potentially serious risk associated with a medication and to enable patients to have continued access to the medication by managing its safe use. The FDA may require a REMS as part of the approval of a new product, or for an approved product when new safety information arises. Activities under a REMS may include (1) providing training on proper prescribing and (2) monitoring improper activities associated with the products related to the program.

**Connecting the Dots**

Certain costs are incurred to facilitate the development of new products or the enhancement/alternative use of existing products, which can lead to new regulatory approvals or the extension of patent protection. These types of costs may be consistent with those involved with “[s]earching for applications of new research findings or other knowledge” (ASC 730-10-55-1(b)) or the “[c]onceptual formulation and design of possible product or process alternatives” (ASC 730-10-55-1(c)) and therefore may be classified as R&D costs. Other types of costs, however, are incurred primarily to yield information (1) that may be useful for expanding access to or the understanding of currently marketed products or (2) as a result of an ongoing compliance program that does not provide significant information that can be used in future R&D. These types of costs may be more appropriately classified as marketing, selling, general, or administrative expenses. It is important for entities to consider all facts and circumstances in determining the proper income statement classification.
Examples of SEC Comments

- Tell us your consideration of ASC 730-10-55-2i in recognizing costs associated with the validation of a patent within Research and development expenses. In your response, tell us the amount you have recorded as Research and development expenses related to patent validation.

- You indicate [that] you have incurred approximately $[X million] in research and development expense related to [Product A], primarily for clinical trial activities and process development and qualification activities. Provide us an analysis under ASC 730-10 supporting your classification of these expenses incurred after FDA approval as research and development expense. In addition, provide further disclosure explaining:
  - [H]ow much related to clinical trial activities and why you incurred these expenses after FDA approval; and
  - [H]ow much related to process development and qualification activities and a more robust description explaining these activities. Distinguish between “manufacturing process development” and “fill/finish process development and qualification” activities, which are terms you use to describe increases/decreases [in your filing].

- The disclosure states R&D expense includes annual FDA fees for maintaining manufacturing sites and legal costs. Please explain to us how these expenses meet the definitions of research or development in ASC 730-10-20 or otherwise comply with ASC 730-10-25 for classifying as R&D expense. Separately tell us the amount of these expenses incurred in each of the last three years and for the [most recent interim period].

- Please tell us the nature of the medical affairs costs you reclassified to research and development expenses during the first quarter . . . as well as the nature of the medical affairs costs you continue to classify as selling, general and administrative expenses. For those costs you now classify as research and development expenses, tell us how these costs represent the discovery of new knowledge or the translation of new knowledge into new products or processes, consistent with the definitions of research and development, respectively, in ASC 730-10-20. Also see ASC 730-10-55-1 and 55-2.

The SEC staff often asks registrants with significant R&D costs to support the classification of the costs comprising the amounts disclosed and explain how the classification is in accordance with ASC 730-10-20. Registrants should be prepared to support their R&D classification by demonstrating careful evaluation of costs under ASC 730.

### 3.2.3 Capitalization of Prelaunch Inventory

Because of the inherent complexities related to product development and manufacturing, life sciences companies may start producing product well in advance of the anticipated product launch date to ensure that there is sufficient plant capacity and available stock to meet forecasted demand. However, the success of new drug (and abbreviated new drug) applications is inherently uncertain, and companies may experience delays in achieving regulatory approval. Consider the following scenarios:

<table>
<thead>
<tr>
<th>Branded Product</th>
<th>Generic Product</th>
<th>Medical Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>A new drug application has been submitted to the FDA for review, and phase III clinical trials have been completed.</td>
<td>An abbreviated new drug application has been submitted to and accepted by the FDA for review.</td>
<td>A 510(k) premarket approval application has been submitted to and accepted by the FDA for review.</td>
</tr>
</tbody>
</table>
In each of the above scenarios, a life sciences entity must use judgment in determining whether costs incurred to manufacture a product in advance of FDA approval should be capitalized as inventory or expensed as incurred. To qualify for capitalization, the prelaunch inventory must qualify as an asset, which is defined in paragraph 26 of FASB Concepts Statement 6 as follows:

An asset has three essential characteristics: (a) it embodies a probable future benefit that involves a capacity, singly or in combination with other assets, to contribute directly or indirectly to future net cash inflows, (b) a particular entity can obtain the benefit and control others' access to it, and (c) the transaction or other event giving rise to the entity's right to or control of the benefit has already occurred.

When evaluating the concept of “probable future benefit” for prelaunch inventory before regulatory approval, a life sciences entity may consider:

- The entity's prior history with approvals of similar products.
- The estimated timing of obtaining regulatory approval.
- Threatened or anticipated litigation challenges (e.g., patent infringement lawsuits).
- FDA correspondence (or other appropriate regulatory agencies) regarding the safety and efficacy of the product.
- Current market factors, including the competitive landscape and pricing.

If capitalization is deemed appropriate, a life sciences entity should continue to monitor the status of the above factors to assess whether capitalization of the product remains appropriate.

### 3.2.3.1 SEC Comment Letter Themes Related to Capitalization of Prelaunch Inventory

<table>
<thead>
<tr>
<th>Example of an SEC Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please disclose the amount of capitalized inventory costs associated with products that have not yet achieved regulatory approval for all periods presented. Please also disclose the following for each product with significant costs capitalized to inventory prior to regulatory approval:</td>
</tr>
<tr>
<td>- [T]he current status of the approval process, including any contingencies needed to be resolved prior to obtaining FDA approval, the risks affecting the probability of obtaining FDA approval, and the estimated timing of obtaining approval;</td>
</tr>
<tr>
<td>- [T]he specific nature of any safety and efficacy, manufacturing, and marketing or labeling issues outstanding and why you do not believe those issues affect its probable future benefit conclusion;</td>
</tr>
<tr>
<td>- [T]he remaining shelf life of each product, as of each balance sheet date presented, and why you believe you will be able to realize the inventory prior to the expiration of the shelf life; and</td>
</tr>
<tr>
<td>- [T]he risks and uncertainties surrounding market acceptance of the product once approved and how this will affect the realization of the asset.</td>
</tr>
</tbody>
</table>

It is important for life sciences companies to provide robust disclosures about capitalizing prelaunch inventory since the SEC staff has historically focused on the capitalization of prelaunch inventory that has not been approved by the FDA. Specifically, the staff has asked registrants to quantify the total amount of capitalized unapproved inventory and clarify their accounting policy for the capitalization of unapproved products. In addition, the staff may ask a registrant to indicate (1) when during the FDA approval process it was concluded that a probable future benefit exists and (2) the status of the FDA's consideration of the safety and efficacy of the product and evaluation of the manufacturing process at that point. Further, a registrant may be asked to explain how its costs qualify as inventory under ASC 330-10-20 and as an asset under paragraph 26 of Concepts Statement 6.
The SEC staff may also request the following additional information or disclosures:

- A description of the overall FDA approval process, including current status, estimated timing of approval, and related risks affecting the approval outcome.
- The remaining shelf life of each capitalized product and why the registrant believes that it will realize the asset’s economic benefit before the expiration of the shelf life.
- The risks and uncertainties associated with market acceptance of the product, once approved, and how these risks and uncertainties will affect the realization of the asset.

### 3.2.4 Nonrefundable Advance Payments

Life sciences entities often prepay for goods or services that will be used in future R&D activities. Payments are often required by CROs in advance of performing clinical trial management services, or by third-party manufacturers to secure manufacturing capacity for the production of a company’s pharmaceutical products. Often, these payments are nonrefundable so that the life sciences entity will not be reimbursed if the CRO’s or manufacturer’s services are unnecessary.

ASC 730-20 provides guidance on nonrefundable advance payments for goods or services that have the characteristics that will be used or rendered for future R&D activities under an executory contractual arrangement. Specifically, ASC 730-20 notes that nonrefundable advance payments for future R&D activities should be deferred and capitalized and subsequently recognized as an expense as the related goods have been delivered or the related services have been performed.

Further, ASC 730-20 requires an entity to (1) continue to evaluate whether it expects the goods to be delivered or services to be rendered and (2) charge to expense any portion of the advance payment that has been capitalized when the entity no longer expects the goods to be delivered or services to be rendered. For example, when a company makes a nonrefundable advance payment to a CRO for the performance of certain R&D services and subsequently decides to abandon the pursuit, management would need to evaluate whether the company will continue to receive R&D services from the CRO and whether the related service period over which the capitalized asset is being amortized remains appropriate. If the CRO will not perform future services, any remaining asset should be expensed. Entities should also note that nonrefundable advance payments for future R&D activities related to materials, equipment, facilities, and purchased intangible assets that have an alternative future use (in R&D projects or otherwise) should be recognized in accordance with the guidance in ASC 730-10.

**Connecting the Dots**

In addition to evaluating the recoverability of any nonrefundable advance payments made to CROs, a life sciences company may need to consider certain external costs incurred after deciding to abandon a clinical trial. For example, the company may owe a CRO additional costs for wind-down activities, termination penalties, and investigator payments. Under ASC 420, for a contract within the scope of that guidance, an entity is required to recognize and measure at fair value a liability for the costs of terminating the contract before the end of the contract term when the entity terminates the contract in accordance with the contract’s provisions (e.g., when the entity gives written notice to the CRO within the notification period specified in the contract or has otherwise negotiated a termination with the CRO). A liability for other costs that will continue to be incurred under a contract for its remaining term without economic benefit to an entity should be recognized and measured at fair value when the entity stops receiving future services.
3.2.5 Refundable Tax Credits for Qualifying R&D Expenditures

To promote innovation and spending in their tax jurisdictions, governments frequently provide tax credits to entities with qualifying R&D expenditures. Sometimes these credits ultimately depend on taxable income, in which case the credits are generally recognized as a reduction of income tax regardless of whether they are accounted for under the flow-through method or the deferral method (as described in ASC 740-10-25-45 and 25-46). However, certain tax jurisdictions provide refundable credits for qualifying R&D that do not depend on the entity’s ongoing tax status or tax position (e.g., an entity may receive a refund despite being in a taxable loss position). Refer to Chapter 8 for additional guidance on when refundable tax credits are within the scope of ASC 740 and accordingly classified within income tax expense (benefit) in the financial statements.

3.2.6 FDA Priority Review Vouchers

Section 524 of the Federal Food, Drug, and Cosmetic Act authorizes the FDA to award priority review vouchers (PRVs) to drug applications for the treatment or prevention of certain tropical or rare pediatric diseases. Once the sponsor obtains a PRV, there is no timeline for use or expiration of the award. While PRVs provide for an expedited review period, they do not guarantee product approval. When initiating the FDA review process, holders of these vouchers can submit them along with their product applications and thereby qualify for a 6-month FDA review period, as opposed to the standard 10-month process. However, companies that plan to use PRVs are required to provide notice to the FDA at least 90 days before they intend to submit their applications and must include in the notice the date by which they expect to deliver their formal applications. Both the tropical and rare pediatric disease PRVs can be transferred (e.g., sold) between companies an unlimited number of times before the FDA review process begins. In recent years, PRV exchanges between companies have ranged in value, with some PRVs commanding prices as high as $350 million.

Questions often arise about whether the amounts paid for these vouchers should be capitalized as an asset or expensed as R&D when such costs are incurred. In determining the appropriate accounting for a PRV, a preparer should consider how the voucher is expected to be used. For example, if a company acquires a PRV specifically to “fast track” the FDA’s review of an existing product in the company’s pipeline, the voucher may not have an alternative future use (e.g., it may be unlikely that the voucher will be sold to another entity). In contrast, if the voucher is acquired with the intent to resell, it may have an alternative future use that could result in probable future economic benefit (i.e., meet the definition of an asset). Companies should carefully consider management’s intent and whether an alternative future use exists when determining how to account for the acquisition of PRVs.

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1 As defined in Sections 524(a)(3) and (a)(4) of the Federal Food, Drug, and Cosmetic Act.
2 As defined in Section 529(a)(3) of the Federal Food, Drug, and Cosmetic Act.
Chapter 4 — Acquisitions and Divestitures

4.1 Introduction

Worldwide, the growing demand for health care services, fueled by aging populations and burgeoning middle classes along with expectations of higher-quality care and a squeeze on funding, is driving a need for new business models. With public finances stretched, governments in countries from the United States and the United Kingdom to Japan, China, and Brazil are rethinking their health care strategies. In such an environment, companies must find new ways to improve the efficiency of their operations, increase their R&D capabilities, tap into alternative sources of innovation, and acquire new customers. As a result of these challenges, significant 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 associated with the “patent cliff.”

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 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

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 clarified by ASU 2017-01 and (2) accounting for transactions after that determination has been made.

4.2.1 Definition of a Business

In January 2017, the FASB issued ASU 2017-01 in response to stakeholder feedback indicating that the definition of a business in ASC 805 was too broad and that too many transactions were qualifying as business combinations even though many of these transactions may have more closely resembled asset acquisitions. Because the definition under legacy U.S. GAAP has been interpreted broadly, it can be difficult and costly to analyze transactions. The amendments in the ASU are intended to make the application of the guidance more consistent and cost-efficient.
Chapter 4 — Acquisitions and Divestitures

The Background Information and Basis for Conclusions of ASU 2017-01 indicates that the amendments are intended to “narrow the definition of a business and provide a framework that gives entities a basis for making reasonable judgments about whether a transaction involves an asset or a business.” In addition, ASU 2017-01 provides examples that illustrate how an entity should apply the amendments in determining whether a set is a business.

ASU 2017-01 became effective for PBEs for annual periods beginning after December 15, 2017. For all other entities, the ASU is effective in annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. The ASU must be applied prospectively on or after the effective date, and no disclosures for a change in accounting principle are required at transition.

Early application is allowed for transactions for which the acquisition or disposal date occurs in a period for which financial statements have not been issued or made available for issuance.

For more information about ASU 2017-01, see Deloitte’s January 13, 2017, Heads Up.

Connecting the Dots
Concerns about the definition of a business were among the primary issues raised in connection with the Financial Accounting Foundation’s May 2013 postimplementation review report on FASB Statement No. 141(R) (codified in ASC 805).

4.2.1.1 Significance of ASU 2017-01
An entity uses the definition of a business in ASC 805 in many areas of accounting, including acquisitions, disposals, goodwill, and consolidation. For example, this distinction is important because the accounting for an asset acquisition significantly differs from the accounting for a business combination.

The FASB considered addressing the concern about the definition of a business more directly by attempting to reduce or eliminate differences in accounting where the definition is relevant. However, to respond to stakeholder concerns in a timely fashion, the FASB decided to begin this project by clarifying the definition of a business. In a future phase of the project, the FASB plans to consider whether there are differences in the acquisition and derecognition guidance for assets and businesses that could be aligned.

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

Since the legacy implementation guidance does not specify the minimum inputs and processes required for a set to meet the definition of a business, some have interpreted the definition of a business broadly. Some have said that a set may qualify as a business even if no processes are acquired when revenue-generating activities continue after an acquisition or if a market participant would be capable of integrating the acquired set with its own processes. For example, some believe that the acquisition of a product right with an in-place supply arrangement meets the definition of a business because a market
participant is capable of acquiring an input (IP with a supply arrangement) and combining it with the market participant's own processes (processes to commercialize the product) to continue generating outputs (product sales). Others have said that the presence of any process can give rise to a business, regardless of the significance of that process.

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

The amendments in ASU 2017-01 address these concerns by (1) providing a “screen” for determining when a set is not a business, (2) adding guidance on the minimum inputs and processes that are needed for an acquired set to be considered a business when the screen's threshold is not met, (3) removing the evaluation of whether a market participant could replace missing elements, and (4) narrowing the definition of the term “output” to make it consistent with how outputs are described in ASC 606.

### 4.2.1.2 Single or Similar Asset Threshold

ASU 2017-01 provides a practical way to determine when a set is not a business. That is, “[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.” When this threshold is met, an entity does not need to evaluate the rest of the implementation guidance. The Background Information and Basis for Conclusions of ASU 2017-01 notes that the assessment may be either qualitative or quantitative. Sometimes, an entity may be able to qualitatively determine that all of the fair value of the acquisition would be assigned to a single asset or a group of similar assets. Paragraph BC19 of ASU 2017-01 offers the following example:

> If the acquisition includes a license for a drug candidate and an at-market contract and the entity concludes that the at-market contract has at the date of assessment little or no fair value assigned to it or the fair value of a single identifiable asset or group of similar identifiable assets is so significant that it is very clear that the threshold will be met, the entity may conclude that the threshold has been met.

An entity may also be able to qualitatively determine that the fair value of the acquisition would be assigned to multiple dissimilar assets, in which case the threshold would not be met. In other cases, an entity may need to perform a quantitative assessment.

In addition, the FASB “decided that the threshold could be met if the fair value is concentrated in a group of similar identifiable assets” (e.g., when “an entity acquires . . . multiple versions of substantially the same asset type instead of precisely one asset”). 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.”

To avoid inappropriate groupings of assets, ASU 2017-01 adds ASC 805-10-55-5C. This paragraph indicates that when 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).” Further, ASC 805-10-55-5C notes that “the following should not be considered similar assets”:

- A tangible asset and an intangible asset
- Identifiable intangible assets in different major intangible asset classes (for example, customer-related intangibles, trademarks, and in-process research and development)
- A financial asset and a nonfinancial asset
Chapter 4 — Acquisitions and Divestitures

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.

ASC 805-10-55-65 through 55-68 (added by ASU 2017-01) illustrate how a life sciences entity would apply the guidance discussed above:

<table>
<thead>
<tr>
<th>ASC 805-10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case B: Acquisition of a Drug Candidate</strong></td>
</tr>
<tr>
<td><strong>Scenario 1</strong></td>
</tr>
<tr>
<td><strong>55-65</strong> 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.</td>
</tr>
<tr>
<td><strong>55-66</strong> 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.</td>
</tr>
</tbody>
</table>

| **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. |
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 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 clinical research organization contracts or clinical manufacturing organization 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.

4.2.1.3 Substantive Process

As noted in paragraph BC35 of ASU 2017-01, the amendments in the ASU also “clarify that an input and a substantive process together are required to significantly contribute to the ability to create outputs. The Board wanted to emphasize that the process must be important to the ability to create outputs to make sure that the bar is not set too low.”

The amendments provide different criteria for entities to evaluate in determining whether a set has a substantive process, depending on whether a set has outputs.

4.2.1.3.1 A Set With No 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. 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, to qualify as a business, a set that does not have outputs “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. ASU 2017-01 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 and ASC 805-10-55-72 (added by ASU 2017-01) illustrate the assessment that a life sciences entity would perform when a set has no outputs:

**ASC 805-10**

<table>
<thead>
<tr>
<th>Case C: Acquisition of Biotech</th>
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</thead>
</table>
| **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.

**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.
4.2.1.3.2 A Set With Outputs

The Background Information and Basis for Conclusions 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 (added by ASU 2017-01) 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.

An organized workforce may signify the existence of a substantive process but would not be required if outputs are present. Paragraph BC51 of ASU 2017-01 states, for example, that “an organized workforce might not be required if the set includes automated processes (for example, through acquired technology, infrastructure, or specialized equipment) or other significant processes that contribute to the ability to continue producing outputs.”

Further, ASC 805-10-55-5F (added by ASU 2017-01) states the following:

<table>
<thead>
<tr>
<th>ASC 805-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

ASC 810-10-55-82 and ASC 810-10-55-84 (added by ASU 2017-01) illustrate the application of the above guidance to arrangements that involve licensing and distribution rights, which are common among life sciences entities:

<table>
<thead>
<tr>
<th>ASC 805-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case F: License of Distribution Rights</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>
Chapter 4 — Acquisitions and Divestitures

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:

- It does not include an organized workforce that could meet the criteria in paragraph 805-10-55-5E(a) through (b).
- There are no acquired processes that could meet the criteria in paragraph 805-10-55-5E(c) through (d).
- It does not include both an input and a substantive process.

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 to support the idea 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 clinical research organization or a clinical manufacturing organization). In such circumstances, the presence of the acquired contract is not relevant to the determination of whether the set has a substantive process. Instead, for the acquired set to represent a business, the acquired set would need to include employees who form an organized workforce and an input that the workforce could develop or convert into output.

4.2.1.4 Definition of Output

The amendments in ASU 2017-01 change the definition of an output to 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.” As explained in the ASU's Background Information and Basis for Conclusions, the definition of outputs was narrowed to be consistent with ASC 606, which “describes goods or services that are an output of the entity’s ordinary activities.” However, not every entity has revenues within the scope of ASC 606. Therefore, the Board decided to incorporate into the definition of output other types of revenues. For example, the reference to investment income in the amendments’ definition of an output was included to ensure that the purchase of an investment company could still qualify as a business combination.

4.2.1.5 Convergence With IFRS Standards

Initially, the definition of a business under ASC 805 was substantially converged with that under IFRS 3. However, in January 2017, the FASB issued ASU 2017-01 to clarify its definition of a business. In October 2018, the IASB issued Definition of a Business (Amendments to IFRS 3), which amended the definition of a business in IFRS 3 to more closely align it with that in ASC 805. While the IASB’s amended definition of a business is not identical to the definition in ASU 2017-01, the IASB amendments’ overall framework for determining whether a set is a business or a group of assets is similar to that of ASU 2017-01. Entities that are subject to IFRS® Standards are required to apply the IASB’s amended definition of a business to acquisitions that occur on or after January 1, 2020.
4.2.1.6 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 A Roadmap to Accounting for Business Combinations.

4.2.2 Asset Acquisitions

In applying the framework in ASU 2017-01, entities must account for transactions that do not meet the definition of a business as asset acquisitions. For such transactions, the accounting requirements related to transaction costs, measurement of assets acquired and liabilities assumed, and recognition of intangible assets may differ from those for business combinations.

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

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

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

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

Q&A 4-1 Accounting for a Business Combination Versus the Acquisition of an Asset Group Determined Not to Be a Business

Question

What are the key differences between the accounting for a business combination and the accounting for an acquisition of an asset group determined not to be a business?
### Answer
The following table summarizes these differences:

<table>
<thead>
<tr>
<th>Issue</th>
<th>Accounting in a Business Combination</th>
<th>Accounting in an Asset Acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>General principle</td>
<td>Fair value model: assets and liabilities are recognized at fair value, with certain exceptions.</td>
<td>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.</td>
</tr>
<tr>
<td>Scope</td>
<td>Acquisition of a business as defined in ASC 805-10.</td>
<td>Acquisition of an asset or a group of assets (and liabilities) that does not meet the definition of a business in ASC 805-10.</td>
</tr>
<tr>
<td>Acquisition-related costs or</td>
<td>Acquisition-related costs are expensed as incurred, except for costs of issuing debt and equity securities, which are accounted for under other GAAP.</td>
<td>Transaction 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.</td>
</tr>
<tr>
<td>transaction costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contingent consideration</td>
<td>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.</td>
<td>Derivatives are recognized at fair value under ASC 815, and equity method investments are recognized on the basis of the guidance in ASC 323-10. Otherwise, such consideration generally is recognized under ASC 450 when it becomes probable and reasonably estimable.</td>
</tr>
<tr>
<td>Goodwill</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Gain from bargain purchase</td>
<td>Recognized in earnings on the acquisition date.</td>
<td>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.</td>
</tr>
<tr>
<td>Issue</td>
<td>Accounting in a Business Combination</td>
<td>Accounting in an Asset Acquisition</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Contingencies</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>Recognized at fair value if they are identifiable (i.e., if they are separable or arise from contractual rights).</td>
<td>Recognized on the basis of relative fair value under ASC 350-10 if they meet the asset recognition criteria in FASB Concepts Statement 5.</td>
</tr>
<tr>
<td>Assembled workforce</td>
<td>Not recognized because it is presumed not to be identifiable.</td>
<td>Recognized because it is presumed to meet the asset recognition criteria in FASB Concepts Statement 5. However, the presence of an assembled workforce may indicate that the acquisition is a business combination rather than an asset acquisition.</td>
</tr>
<tr>
<td>IPR&amp;D</td>
<td>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.</td>
<td>Expensed under ASC 730 unless the IPR&amp;D has an alternative future use.</td>
</tr>
<tr>
<td>Deferred taxes</td>
<td>Generally recognized for most temporary book/tax differences related to assets acquired and liabilities assumed under ASC 740.</td>
<td>Generally recognized for temporary book/tax differences in an asset acquisition by using the simultaneous equations method in accordance with ASC 740.</td>
</tr>
</tbody>
</table>
| 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. |
(Table continued)

<table>
<thead>
<tr>
<th>Issue</th>
<th>Accounting in a Business Combination</th>
<th>Accounting in an Asset Acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement period</td>
<td>In accordance with ASC 805-10-25-13, the acquirer reports provisional amounts for the items for which the accounting &quot;is incomplete by the end of the reporting period in which the combination occurs&quot; and is allowed up to one year to adjust those provisional amounts. This time frame is referred to as the measurement period.</td>
<td>ASC 805-50 does not address a measurement period in the context of an asset acquisition.</td>
</tr>
</tbody>
</table>

4.2.2.1 Cost of the Acquisition

In a business combination, the fair value of the consideration transferred excludes the transaction costs; in an asset acquisition, transaction costs are generally included in the cost of the acquisition. In addition, contingent consideration in an asset acquisition is not accounted for in accordance with ASC 805-30-25-5 through 25-7. Contingent consideration is measured in accordance with other applicable GAAP, such as ASC 450 and ASC 815.

4.2.2.2 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 would 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.

4.2.2.2.1 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.” For example:

- “[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.”

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.”

Connecting the Dots

We understand that in the absence of a final consensus on EITF Issue 09-2, some continue to analogize to the guidance in Statement 141 when accounting 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). Paragraph 27 of Statement 141 provided that “contingent consideration usually should be recorded when the contingency is resolved and consideration is issued or becomes issuable.”

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., property, plant, and equipment (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.

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1 Statement 141 was superseded by Statement 141(R), which is codified in ASC 805.
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 includes a contingent consideration arrangement, an entity may 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). That guidance states that if an entity acquires an equity method investment in which the fair value of its share of the investee’s net assets exceeds its initial cost and the agreement includes contingent consideration, the entity recognizes a liability equal to the lesser of:

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

Like acquisitions of equity method investments, asset acquisitions are accounted for under a cost accumulation model. Therefore, we believe that the guidance above could be applied to asset acquisitions by analogy. (However, if the contingent payment is related to IPR&D assets with no alternative future use, the amount of the contingent payment would be expensed, as illustrated in the example within Q&A 4-2.) 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).

4.2.2.3 Allocating the Cost

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, pro rata allocation either 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.

4.2.2.3.1 Exceptions to Pro Rata Allocation

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 the example within Q&A 4-2).

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 investments accounted for under the equity method).
- 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.
**Example 4-1**

**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:

<table>
<thead>
<tr>
<th>Fair Value (ASC 820)</th>
<th>Percentage of Fair Value*</th>
<th>Cost of the Acquisition</th>
<th>Allocated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>$20,000</td>
<td>29%</td>
<td>$90,000</td>
</tr>
<tr>
<td>Building</td>
<td>50,000</td>
<td>71%</td>
<td>$90,000</td>
</tr>
<tr>
<td>Indefinite-lived intangible asset</td>
<td>30,000</td>
<td>30,000</td>
<td></td>
</tr>
</tbody>
</table>

*$ 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, 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 4-2**

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

Assume the same facts as in Example 4-1, except that the total cost of the acquisition, including transaction costs, is $90,000. Company A's cost is allocated as follows:

<table>
<thead>
<tr>
<th>Fair Value (ASC 820)</th>
<th>Percentage of Fair Value*</th>
<th>Cost of the Acquisition Less Ineligible Asset</th>
<th>Allocated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>$20,000</td>
<td>29%</td>
<td>$60,000</td>
</tr>
<tr>
<td>Building</td>
<td>50,000</td>
<td>71%</td>
<td>$60,000</td>
</tr>
<tr>
<td>Indefinite-lived intangible asset</td>
<td>30,000</td>
<td></td>
<td>30,000</td>
</tr>
</tbody>
</table>

*$ 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, 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 4-3**

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

Assume the same facts as in Example 4-1, except that the total cost of the acquisition, including transaction costs, is $90,000. Company A's cost is allocated as follows:

<table>
<thead>
<tr>
<th>Fair Value (ASC 820)</th>
<th>Percentage of Fair Value*</th>
<th>Cost of the Acquisition</th>
<th>Allocated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machinery and equipment</td>
<td>$ 20,000</td>
<td>20%</td>
<td>$ 90,000</td>
</tr>
<tr>
<td>Building</td>
<td>50,000</td>
<td>50%</td>
<td>$ 90,000</td>
</tr>
<tr>
<td>Indefinite-lived intangible asset</td>
<td>30,000</td>
<td>30%</td>
<td>$ 90,000</td>
</tr>
<tr>
<td>$ 100,000</td>
<td></td>
<td></td>
<td>$ 90,000</td>
</tr>
</tbody>
</table>

* 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.

**Q&A 4-2 Allocating the Cost of an Asset Acquisition of IPR&D When Fair Value Exceeds Cost**

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

**Example**

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.

**Question**

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

As observed 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, 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 in which the future milestone payment that otherwise may have been recorded on a later date (i.e., when it was otherwise probable that the milestone would be achieved and most likely capitalized since the milestone payment is triggered only upon regulatory approval) would need to be expensed as IPR&D as of the acquisition date. In such a narrow fact pattern, in which the acquisition is entirely attributable to IPR&D that must be expensed as of the acquisition date, A’s conclusion not to recognize the contingent milestone payment is reasonable under the circumstances.

4.2.2.4 Nonfinancial Assets (or In-Substance Nonfinancial Assets) Used as Consideration

In February 2017, the FASB issued ASU 2017-05 (codified in ASC 610-20), which amended the “Acquisition of Assets Rather Than a Business” subsections of ASC 805-50 to clarify that “[i]f the consideration given is nonfinancial assets or in substance nonfinancial assets within the scope of Subtopic 610-20 . . . , the assets acquired shall be treated as noncash consideration and any gain or loss shall be recognized in accordance with Subtopic 610-20.” Therefore, if the assets given as consideration are nonfinancial assets (or in-substance nonfinancial assets), an entity should apply the guidance in ASC 610-20 rather than ASC 805-50.

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.” In addition, 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.
ASU 2017-05 also clarifies the accounting for partial sales of nonfinancial assets. An entity derecognizes a distinct nonfinancial asset (or distinct in-substance nonfinancial asset) in a partial sale transaction when it (1) does not have (or ceases to have) a controlling financial interest in the legal entity that holds the asset in accordance with ASC 810 and (2) transfers control of the asset in accordance with ASC 606. Once control is transferred, any noncontrolling interest received (or retained) is measured at fair value. (Before the adoption of ASC 610-20, if the consideration given is real estate, the transaction may be within the scope of ASC 360-20 on real estate sales, which may limit or preclude recognition of a real estate sales transaction or a gain on the sale.)

In addition, ASU 2017-05 amended ASC 610-20 to clarify that it does not apply to nonmonetary transactions within the scope of ASC 845. We believe that it may be challenging to determine whether an exchange of noncash assets is a nonmonetary exchange within the scope of ASC 845 or an exchange of nonfinancial assets within the scope of ASC 610-20 (once effective), and ASU 2017-05 provides no additional guidance on how to make this determination. However, we also believe that the definition of nonmonetary assets and liabilities is broader than the definitions of nonfinancial assets and in-substance nonfinancial assets.

Entities are required to adopt ASC 610-20 at the same time that they adopt ASC 606. See Deloitte’s *A Roadmap to Applying the New Revenue Recognition Standard* for more information.

### 4.2.2.5 Nonmonetary Exchanges

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. In a transaction in which it is determined that assets (rather than businesses) are being swapped and the transaction is not within the scope of ASC 610-20 (once effective), an entity should consider whether the transaction is a nonmonetary exchange within the scope of ASC 845. The ASC master glossary defines nonmonetary assets and liabilities as “assets and liabilities other than monetary ones” and notes that such assets and liabilities include “inventories; investments in common stocks; property, plant, and equipment; and liabilities for rent collected in advance.”

In a nonmonetary exchange, the acquiring entity (1) derecognizes the assets given, (2) recognizes the nonmonetary assets received, which it measures by using the fair value of the assets given (unless the fair value of the assets received is more clearly evident than the fair value of the assets given), and (3) recognizes a gain or loss for the difference between the amounts in (1) and (2). This is similar to the general principle in ASC 850-50 for measuring the cost of an asset acquisition (as discussed above); however, for nonmonetary exchanges, there are three exceptions under ASC 845-10-30-3, which prohibits the use of fair value and gain or loss recognition if (1) the “fair value of neither the asset(s) received nor the asset(s) relinquished is determinable within reasonable limits,” (2) the “transaction is an exchange . . . to facilitate sales to customers,” or (3) the “transaction lacks commercial substance.” If any of these exceptions applies, 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).

In addition, before an entity adopts the guidance in ASU 2017-05, its gain may be limited if the entity (1) transfers a nonmonetary asset whose readily determinable fair value exceeds the carrying amount to another entity in exchange for a noncontrolling ownership interest in that entity and (2) accounts for that ownership interest by using the equity method.
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., retaining 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 commercial (finished goods) 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 commercial 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.

4.2.2.6 Share-Based Payments

To complete the acquisition of various assets (e.g., patents, licensing arrangements) accounted for as asset acquisitions, a life sciences company may finance the arrangement by settling the transaction in its own publicly issued equity (or other equity instruments) rather than other traditional consideration.

In June 2018, the FASB issued ASU 2018-07, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on share-based payments granted to nonemployees is aligned with the requirements for share-based payments granted to employees. Accordingly, the ASU supersedes ASC 505-50 and expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. See Chapter 9 for further discussion of the ASU.
4.2.2.7 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 company may enter into contemporaneous supply arrangements for 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. 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, even though the guidance does not explicitly say so. 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 4-4

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 4-5

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.

In prepared remarks at the 2007 AICPA Conference on Current SEC and PCAOB Developments, Eric West, then associate chief accountant in the SEC’s Office of the Chief Accountant, discussed a fact pattern in which a company pays cash and conveys licenses to a plaintiff to settle a claim related to patent infringement and misappropriation of trade secrets. In exchange, the company receives a promise to drop the patent infringement lawsuit, a covenant not to sue with respect to the misappropriation of trade secrets claim, and a license to use the patents subject to the litigation.
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Mr. West noted that “[t]o properly account for this arrangement, a company must identify each item given and received and determine whether those items should be recognized.” In addition, Mr. West stated the following regarding the valuation of the elements of the transaction:

[W]e believe that it would be acceptable to value each element of the arrangement and allocate the consideration paid to each element using relative fair values. To the extent that one of the elements of the arrangement just can’t be valued, we believe that a residual approach may be a reasonable solution. In fact, we have found that many companies are not able to reliably estimate the fair value of the litigation component of any settlement and have not objected to judgments made when registrants have measured this component as a residual. In a few circumstances companies have directly measured the value of the litigation settlement component. In the fact pattern that I just described, the company may be able to calculate the value of the settlement by applying a royalty rate to the revenues derived from the products sold using the patented technology during the infringement period. Admittedly, this approach requires judgment and we are willing to consider reasonable judgments.

Accordingly, we believe that the elements of the transaction should be valued on the basis of relative fair values unless the fair value of one of the elements cannot be estimated. In that case, a residual approach may be acceptable.

For additional information, see Deloitte’s A Roadmap to Accounting for Business Combinations.

4.2.3 Business Combinations

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.

Q&A 4-3 Whether to Recognize Intangible Assets Apart From Goodwill for IPR&D Activities Acquired in a Business Combination

Question

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

Answer

Yes. Under ASC 805 and ASC 350, the acquiring entity recognizes acquired IPR&D at fair value as of the acquisition date and subsequently accounts for it as an indefinite-lived intangible asset until completion or abandonment of the associated R&D efforts.
For IPR&D to be recognized as of the acquisition date, the costs incurred by the acquiree must be for R&D activities within the scope of ASC 730. (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

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 new line of products, all of which it expensed as incurred under ASC 730. Company A plans to continue these R&D efforts in hopes of releasing the new line of products into the market.

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

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

4.2.3.2 Identifying IPR&D

Q&A 4-4 Considerations for Identifying IPR&D

Question

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

Answer

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.
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 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.

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

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 Abbreviated New Drug Application 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).

4.2.3.3 Defensive IPR&D Acquired in a Business Combination

In completing an M&A transaction, a life sciences company may acquire an IPR&D asset even though it does not intend to pursue the R&D project to completion. Instead, the company 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 company’s portfolio.

2 “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.”
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 company would assign the IPR&D asset's fair value as of the measurement date based on the perspective of a market participant. See Example 1, Case C, “In-Process Research and Development Project” in ASC 820-10-55-32 for further discussion of valuation considerations based on the facts and circumstances related to the defensive IPR&D.

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 Q&A below, which is adapted from paragraph 2.33 of the AICPA Guide.

**Q&A 4-5 Recording and Subsequent Measurement of Acquired IPR&D Assets Held for Defensive Purposes**

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.

**Question**

What are the relevant “day 1” and “day 2” accounting considerations for recording and subsequently measuring the patented technology and know-how of B?

**Answer**

To the IPR&D assets acquired from B, A would assign a fair value in a manner consistent with that of a market participant, as well as indefinite life.
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). It should be noted 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) and 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

#### Q&A 4-6 Considerations for Evaluating Acquired Intangible Assets That May Be Outlicensed to Others

**Question**

What considerations should an entity take into account when evaluating acquired intangible assets that may be outlicensed to others?

**Answer**

The AICPA Guide specifically addresses outlicensing arrangements. Paragraph 2.10 states, in part:

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

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

In light of the above, we expect that there will be circumstances in which an outlicensed R&D project should be accounted for as a contract-based intangible asset (as defined in ASC 805-20-55-31) rather than an IPR&D asset. This determination is important because an R&D activity that constitutes IPR&D is accounted for as an indefinite-lived intangible asset (until completion or abandonment of the R&D efforts) in connection with a business combination. In contrast, a contract-based intangible would typically be accounted for as a definite-lived intangible asset (subject to amortization).
For example, assume that the 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. Judgment is required in the determination of the unit of account to be used for acquired IPR&D given that certain separately identifiable IPR&D assets that share similar characteristics are sometimes 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.”
Example 4-6

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. All clinical trials have been completed in the European Union (EU) and the appropriate applications have been filed, but the product is awaiting regulatory approval. However, the same product is under development in the United States and is not as far advanced there. In the United States, the product has only just commenced phase III clinical trials. In addition, if the product is approved, patent protection is expected to expire significantly later than in the EU.

Given the above factors, X determines that two IPR&D assets should be recognized: one for the EU 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 remained 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.

4.2.3.6 Subsequent Accounting for Acquired IPR&D Assets

Q&A 4-7 Accounting for Acquired IPR&D Assets After Recognition in a Business Combination

Question

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

Answer

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

During the period that [the acquired IPR&D intangible] assets are considered indefinite lived, they shall not be amortized but shall be tested for impairment in accordance with 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 1

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

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

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

From June 30, 20X1, to June 30, 20Y2, 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, 20Y2 (the date of abandonment), in the income statement.

Example 2

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

In this case, A must assess the useful life of the acquired IPR&D asset as of July 1, 20Y2 (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, 20Y2.

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.
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.

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.

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.

What factors may be relevant to life sciences entities when they perform a qualitative impairment assessment of IPR&D assets?

Life sciences entities may encounter various challenges in performing an impairment assessment of IPR&D assets. The entities may 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? Is there any change 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 and 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.

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 codevelop or copromote a particular compound.

Q&A 4-9 How to Account for a Preexisting Relationship That Was Settled as a Result of a Business Combination

Question

How should an entity account for a preexisting relationship that is treated as having been settled as a result of a business combination?

Answer

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

### 4.2.3.9 Initial and Subsequent Accounting for Contingent Consideration

**Q&A 4-10 How to Initially Account for Contingent Consideration in a Business Combination**

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

**Answer**
In accordance with ASC 805-30-25, contingent consideration is recorded at fair value as part of the total consideration transferred by the acquirer. The acquirer must distinguish between contingent consideration (see ASC 805-10-20) and preexisting contingencies assumed in the acquisition (see ASC 450-10-20). The fair value of contingent consideration is considered 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).

**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.

**Q&A 4-11 How to Subsequently Account for Contingent Consideration in a Business Combination**

**Question**
How should an entity subsequently account for contingent consideration in a business combination?
**Answer**

If the acquirer classifies a contingent consideration arrangement as an asset or a liability, it 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.

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**

Company A acquires Company B for $15 million. 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.
4.2.3.10 SEC Comment Letter Themes Related to Business Combinations

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.

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

4.2.3.10.1 Business Combination Versus Asset Acquisition Accounting Determination

<table>
<thead>
<tr>
<th>Examples of SEC Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>• You recorded the February and December 2017 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. In this regard, please specifically address the following:</td>
</tr>
<tr>
<td>• As it appears you acquired both tangible and intangible assets in the February acquisitions and the December 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.</td>
</tr>
<tr>
<td>• 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.</td>
</tr>
<tr>
<td>• Please provide us your analysis of how you concluded under ASU 2017-01 and ASC 805-10-55 that [Transaction A] should be accounted for as an asset acquisition, rather than a business combination. Your analysis should include details of any assets, liabilities, contracts, agreements, employees or other items transferred under this transaction. Please also explain to us how you considered the research and development programs discussed in Note [X] to the [target] financial statements included in Exhibit [Y].</td>
</tr>
</tbody>
</table>

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 ASU 2017-01 (effective for PBEs for annual periods beginning after December 15, 2017) and 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 continue to focus on whether an acquired set meets the definition of a business after adoption of ASU 2017-01.
4.2.3.10.2  Purchase Price Allocation

### Examples of SEC Comments

- You disclose . . . that you capitalized the entire consideration as patents and intellectual property to be amortized over the legal remaining patent life. However, it appears that the [acquired] product was a clinical stage drug candidate. Please address the following:
  - Tell us how you considered whether any of the purchase price should have been allocated to other assets or in-process research and development.
  - Tell us how your accounting treatment complies with ASC 805-50 and ASC 730-10-25-1.
  - Support your conclusion that the intangible asset you have recorded has alternative future use.
- In your disclosure . . . , you indicate that you acquired $[X] million of intangible assets from [the target company]. Please identify for us the specific intangible assets acquired and their amounts, and describe for us how you determined the fair value of each asset. Tell us why you do not disaggregate these assets or provide more detail of the components of these assets in your disclosure.
- Please revise [your disclosure] to present your purchase price allocation based on the total consideration transferred instead of total cash paid.

Registrants need to consider the provisions of ASU 2017-01 and 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.

4.2.3.10.3  Useful Life 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.
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. However, the useful life could be affected by other factors, such as the risk of competition from branded or generic products before the company’s patent expires or a high barrier to market entry even after the company’s patent expires. The SEC staff has asked registrants to provide additional analysis that explains the basis for their conclusions about the useful life of acquired intangible assets and how their determination of useful life aligns with the period of economic benefit from the assets.

4.2.3.10.4 Contingent Consideration

Contingent consideration arrangements are common in business combinations 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 about facts or circumstances that existed as of the acquisition date) or in current earnings under ASC 805-10-25-13 through 25-19 and ASC 805-10-30-3. 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 Divestitures

The determination of whether a group of assets represents a business is important not only in acquisitions but also in divestitures. Specifically, in divestiture transactions related to the disposal of a business, a company has the option of electing different accounting alternatives and using them as a precedent for future transactions. The accounting policy described in the Q&A below is relevant only to groups of assets that meet the definition of a business. For considerations related to the sale of assets, see Q&A 2-4, which discusses the accounting for asset dispositions under the new 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.

Q&A 4-12 Seller’s (Parent’s) Accounting for Contingent Consideration Upon Deconsolidation of a Subsidiary or Derecognition of a Group of Assets That Is a Business

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

This applies only to arrangements in which the payment is contingent consideration. Further, it is assumed in this Q&A that the seller has determined that the arrangement does not meet the definition of a derivative instrument. If the arrangement met the definition of a derivative, it would be accounted for under ASC 815.

Question

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

Answer

This topic is discussed in EITF Issue No. 09-4. At the EITF’s meeting on September 9–10, 2009, the EITF considered the two approaches discussed below with respect to a seller’s accounting for a contingent consideration arrangement upon deconsolidation of a subsidiary or derecognition of a group of assets that meets the definition of a business; however, the Task Force did not reach a consensus on this Issue. Accordingly, in the absence of future standard setting, there may be diversity in practice regarding a seller’s accounting for a contingent consideration arrangement. Nevertheless, entities should establish an accounting policy for the initial and subsequent measurement of 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.
Approach 1

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

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

Approach 2

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

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

Example

Parent A has a wholly owned subsidiary 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:

<table>
<thead>
<tr>
<th></th>
<th>Approach 1</th>
<th>Approach 2</th>
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</thead>
<tbody>
<tr>
<td>Cash proceeds</td>
<td>$150</td>
<td>$150</td>
</tr>
<tr>
<td>Contingent consideration receivable</td>
<td>30</td>
<td>—</td>
</tr>
<tr>
<td>Total consideration</td>
<td>180</td>
<td>150</td>
</tr>
<tr>
<td>Less: subsidiary's carrying amount</td>
<td>(100)</td>
<td>(100)</td>
</tr>
<tr>
<td>Initial gain on sale</td>
<td>$80</td>
<td>$50</td>
</tr>
</tbody>
</table>
4.3 New Accounting Standard — Accounting for Goodwill Impairment (ASU 2017-04)

4.3.1 Background

In January 2014, the FASB issued ASU 2014-02, which provided an accounting alternative initially developed by the Private Company Council (PCC) that allowed eligible private companies to amortize goodwill and perform a simplified impairment test. Feedback received by the Board on the PCC accounting alternative indicated that many public companies and NFPs shared similar concerns with respect to the cost and complexity of the annual goodwill impairment test. In response to this feedback, the FASB added to its agenda a two-phase goodwill simplification project. In October 2016, the Board decided to suspend deliberations of phase 2 and move that portion of the project to its research agenda. A few months later, in January 2017, the FASB issued ASU 2017-04 as part of phase 1. Before evaluating whether to make any additional changes to the model for the subsequent accounting for goodwill, the Board will evaluate the effectiveness of ASU 2017-04 and continue to monitor the IASB’s projects on goodwill and impairment.

The guidance in ASU 2017-04 is summarized below.

4.3.2 Key Provisions

ASU 2017-04 most notably removes “step 2” from the impairment model, thus eliminating the requirement for entities to complete a hypothetical purchase price allocation.

The FASB also determined not to give entities the option of performing step 2 and to instead require them to adopt the simplified impairment test prospectively. Therefore, under the amendments in ASU 2017-04, entities would perform their annual (or any necessary interim) goodwill test by comparing the fair value of a reporting unit with its carrying amount. Entities would recognize any impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value (not to exceed the carrying amount of goodwill allocated to the reporting unit). Entities still have the option of performing the qualitative assessment for reporting units to determine whether a quantitative impairment test is necessary.

In addition, ASU 2017-04 requires entities to apply the same impairment model for a reporting unit with a zero or negative carrying amount as the model for a reporting unit with a positive carrying amount by comparing the fair value of the reporting unit with its carrying amount. Further, entities are required to quantitatively disclose the amount of goodwill allocated to reporting units with zero or negative carrying amounts.

ASU 2017-04 also:

- Clarifies the requirements for excluding and allocating foreign currency translation adjustments to reporting units related to an entity’s testing of reporting units for goodwill impairment.
- Clarifies that “an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.”
4.3.3 Effective Date and Transition

For PBEs that are SEC filers, ASU 2017-04 is effective for annual and any interim impairment tests for periods beginning after December 15, 2019. PBEs that are not SEC filers should apply the new guidance to annual and any interim impairment tests for periods beginning after December 15, 2020. For all other entities, including NFPs, ASU 2017-04 is effective for annual and any interim impairment tests for periods beginning after December 15, 2021. Early adoption is allowed for all entities as of January 1, 2017, for annual and any interim impairment tests occurring on or after January 1, 2017. The ASU must be adopted on a prospective basis.

For more information about ASU 2017-04, see Deloitte's February 1, 2017, *Heads Up*. 
Chapter 5 — Consolidation

5.1 Introduction

Life sciences entities enter into a variety of arrangements with other parties to facilitate the research, development, or sale of their IP or products. Because life sciences entities may absorb the risks and rewards of other parties through interests other than those based on traditional voting equity, they must carefully analyze their arrangements with those parties to determine whether to consolidate them. However, it is important to note that the guidance discussed in this chapter is only applicable to arrangements that are structured in a separate legal entity and is not applicable to collaborative arrangements because those arrangements are not structured in a separate legal entity. See Section 2.2.1 for accounting considerations relevant to collaborative arrangements.

The dual consolidation model under U.S. GAAP, which comprises the variable interest entity (VIE) model and the voting interest entity model, is designed to ensure that the reporting entity that consolidates another legal entity has (1) the obligation to absorb losses of, or the right to receive benefits from, the legal entity that could potentially be significant to the legal entity and (2) the power to direct the activities that most significantly affect the legal entity’s economic performance.

5.2 Consolidation Decision Trees

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

5.3 Industry Issues

The discussions and examples below contain guidance on consolidation matters that frequently affect life sciences entities. The guidance cited is not intended to be all-inclusive or comprehensive; rather, it provides targeted considerations that are most relevant to the industry. To complete a consolidation analysis, entities must consider all facts and circumstances and use significant judgment. The examples cited will be beneficial in introducing concepts as you approach the evaluation of variable interests.

5.3.1 Scope Exceptions to the Consolidation Guidance — Business Scope Exception

A reporting entity should evaluate whether it can apply any of the general scope exceptions to the consolidation guidance or the scope exceptions to the VIE model. The most frequently cited exception is the so-called business scope exception. (For a list of all consolidation and VIE scope exceptions, see Chapter 3 of Deloitte’s Consolidation Roadmap.)
The business scope exception is two-pronged and premised on both (1) the legal entity's characteristics (i.e., the nature of the legal entity's activities and whether it is a business as defined in ASC 805) and (2) the reporting entity's relationship with the legal entity (i.e., the extent of involvement by the reporting entity in the design or redesign of the legal entity, whether the legal entity is designed so that substantially all of its activities either involve or are conducted on behalf of the reporting entity and its related parties, and whether the reporting entity and its related parties provided more than half of the subordinated financial support). A common oversight in evaluating the applicability of the business scope exception is merely assessing whether a legal entity meets the definition of a business and failing to assess the nature of the legal entity's activities and the conditions outlined in the second prong of the test. Two of the more common relationships that must be analyzed are described below.

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

A reporting entity should base its determination of whether substantially all of a legal entity's activities either involve or are conducted on behalf of the reporting entity and its related parties on the design of the legal entity and should compare the nature and extent of the activities between the reporting entity and the legal entity with the entire set of the legal entity's activities. Generally, if 90 percent or more of the legal entity's activities are conducted on behalf of a reporting entity and its related parties, it is presumed to be “substantially all” of the legal entity's activities. However, less than 90 percent is not a safe harbor. While a variety of circumstances may indicate that substantially all of the activities of a legal entity are conducted on behalf of a reporting entity, in the context of the life sciences industry, one such circumstance would be when a reporting entity holds the rights to products that result from the R&D of a legal entity.

Example 5-1

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

5.3.1.2 Additional Subordinated Financial Support — Put and Call Options

Put and call options may exist in agreements between equity owners in a life sciences legal entity (e.g., between joint venture partners). Such options can have an impact on whether a reporting entity meets the condition in ASC 810-10-15-17(d)(3) and, therefore, on whether it can apply the business scope exception. The examples below illustrate situations in which (1) a put option (purchased by one investor from the reporting entity) results in the reporting entity's ineligibility for the business scope exception since the reporting entity effectively provides more than half of the total equity, subordinated debt, and other forms of subordinated financial support to the legal entity and (2) a call option would not have the same impact.

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1 As discussed in Section 4.2.1, ASU 2017-01 narrows the definition of a business and is intended to reduce the number of legal entities that will be deemed businesses once the standard is adopted. We do not believe that a reporting entity is generally required upon adoption of ASU 2017-01 to reassess whether a legal entity that previously applied the business scope exception continues to meet the definition of a business.
Example 5-2

Put Option

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

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

Example 5-3

Call Option

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

The fair value of the fixed-price call option should not be considered additional subordinated financial support to X because A will not absorb expected losses of X upon exercise of that call option (i.e., the option does not meet the definition of subordinated financial support in ASC 810-10-20). Investor A can exercise its call and obtain additional residual returns of X, but the call option does not expose it to additional expected losses. Therefore, A would not consider the fair value of the fixed-price call option in determining whether it meets the condition in ASC 810-10-15-17(d)(3). Investors A and B would not meet this condition since the fair value of the equity provided by each investor would not constitute more than half of the total of the equity, subordinated debt, and other forms of subordinated financial support to the legal entity. To use the business scope exception, A and B must determine whether the other conditions in ASC 810-10-15-17(d) are met.
Chapter 5 — Consolidation

5.3.2 Identifying Variable Interests

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

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

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

<table>
<thead>
<tr>
<th>Types of Variable Interests</th>
<th>Illustrative Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term liabilities of a legal entity (e.g., fixed-rate debt, floating-rate debt, mandatorily redeemable preferred stock)</td>
<td>Aspen Co. (the reporting entity) lends Dunne Co., a biotech firm, $50 million in the form of a five-year fixed-rate unsecured loan. Aspen Co., as a debt holder, absorbs the variability in the value of Dunne Co.’s net assets exclusive of variable interests because Aspen Co. is exposed to Dunne Co.’s ability to pay (i.e., credit risk) and may also be exposed to interest rate risk depending on the design of the legal entity.</td>
</tr>
<tr>
<td>Equity of a legal entity (e.g., mezzanine equity, preferred stock, common stock, partnership capital)</td>
<td>Schrute LP (the reporting entity) invests $89 million in Michael Co., a CRO. The equity investment was made in common stock and is considered equity at risk under ASC 810-10-15-14(a) (which is further discussed below). Schrute LP’s interest in Michael Co. is a variable interest that absorbs the variability associated with changes in Michael Co.’s net assets exclusive of variable interests.</td>
</tr>
<tr>
<td>Guarantees written by a reporting entity²</td>
<td>Costanza Inc. (the reporting entity) provides a guarantee to a medical device company, Ball Investments Inc., on the $2 billion fair value of all medical device IP held by Ball Investments Inc. Costanza Inc. must pay Ball Investments Inc. for any decreases in value of this IP. The guarantee agreement transfers all or a portion of the risk of specified assets (IP) to Costanza Inc.; thus, Costanza Inc. has a variable interest in Ball Investments Inc.</td>
</tr>
</tbody>
</table>

² ASC 810-10-25-55 and 25-56 indicate that variable interests in a specified asset whose value is less than half of the total fair value of a VIE’s assets are not considered variable interests in that legal entity unless the reporting entity also holds another interest in the legal entity. In addition, a variable interest in a specified asset of a VIE could result in consolidation of a “silico” within the VIE. For further discussion, see Section 4.3.11 and Chapter 6 of Deloitte’s Consolidation Roadmap.
(Table continued)

<table>
<thead>
<tr>
<th>Types of Variable Interests</th>
<th>Illustrative Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Put options written by a reporting entity and similar arrangements on specified assets owned by the legal entity³</td>
<td>Hermanos LLC (the reporting entity) writes a put option to White Inc. allowing White Inc. to sell its medicinal compound in development for a fixed price at a later date. Hermanos LLC has a variable interest in the specified assets of White Inc. since Hermanos LLC is exposed to variability in the values of the medicinal compound.</td>
</tr>
<tr>
<td>Stand-alone call options written by the legal entity on specified assets owned by that legal entity⁴</td>
<td>Sterling Inc. writes a call option on its wholly owned interest in a treatment in phase II clinical trials to Draper LP (the reporting entity), allowing Draper LP to acquire the interest for a fixed price at a later date. Because Draper LP participates in the positive variability of the specified assets of Sterling Inc., Draper LP possesses a variable interest in those specified assets.</td>
</tr>
<tr>
<td>Fees paid to a decision maker or service provider</td>
<td>Snow LLC pays a fee to Red Corp. (the reporting entity) to distribute Snow LLC's products. The fee arrangement requires Snow LLC to pay Red Corp. all profits earned on the distribution of the products. In accordance with ASC 810-10-55-37C, the fee arrangement is designed to transfer substantially all of the residual returns and risks of ownership of Snow LLC's products to Red Corp., the decision maker. Red Corp.'s earned fee represents a variable interest in Snow LLC.</td>
</tr>
<tr>
<td>Contingent payments made to a reporting entity</td>
<td>Caspian Inc. (the reporting entity) holds rights to a pharmaceutical drug. Wilson Inc. obtains a license from Caspian Inc. to produce, market, and sell the drug, and Caspian Inc. will earn a royalty based on Wilson Inc.'s sales. Caspian Inc. holds a variable interest in Wilson Inc. because it absorbs variability through the royalty.</td>
</tr>
</tbody>
</table>

The table below lists examples (not all-inclusive) of what generally would not be considered variable interests.

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

Discussion of the by-design approach for identifying variable interests, along with a more expansive list of illustrative examples of variable interests, is included in Chapter 4 of Deloitte's Consolidation Roadmap.

³ See footnote 2.
⁴ See footnote 2.
5.3.3 Determining Whether a Legal Entity Is a VIE

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

Legal entities can differ in structure as well as legal form (e.g., corporations compared with limited partnerships and similar entities), which affects the method used to understand their design and purpose. In simple terms, the distinction is based on the nature and amount of the equity investment and the rights and obligations of the equity investors. If a legal entity has sufficient equity investment at risk to finance its operations, and those equity investors, through their equity investment at risk, make decisions that direct the significant activities of the legal entity, consolidation based on majority voting interest is generally appropriate. However, if equity is not sufficient, or the equity investors do not control the legal entity through their equity investment, the VIE model is used to identify the appropriate party, if any, to consolidate.

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

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

Sections 5.3.3.1 through 5.3.3.3 below discuss a brief list of considerations specifically relevant to life sciences entities for determining whether the legal entity is a VIE. Since this list is not all-encompassing, we encourage you to refer to Chapter 5 of Deloitte’s Consolidation Roadmap during your analysis.

5.3.3.1 The Legal Entity Does Not Have Sufficient Equity Investment at Risk

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

5.3.3.1.1 Determining Whether the Equity Investment Is “At Risk”

An interest classified as equity may not have the substantive characteristics of equity. Since the VIE consolidation framework is intended to apply to entities whose voting interests may not be the most appropriate determining factor in the identification of which party should consolidate, the FASB reasoned that equity interests that are not “at risk” should not be included in the sufficiency-of-equity test. To be considered part of the equity investment at risk, equity interests must (1) participate significantly in profits and losses, (2) not be issued in exchange for subordinated interests in other VIEs, (3) not be received from the legal entity or parties involved with the legal entity unless that party is a parent, a subsidiary, or an affiliate of the investor that is required to be included in the same set of consolidated financial statements as the investor, and (4) not be financed by the legal entity or other parties involved with the legal entity unless that party is a parent, a subsidiary, or an affiliate of the investor that is required to be included in the same set of consolidated financial statements as the investor. Further, equity investments acquired by an equity investor in exchange for promises to perform services cannot be considered equity investment at risk; this is because the equity is received
in lieu of a fee for services to be performed. Similarly, equity investments acquired as a result of past services performed are not considered equity investment at risk.

**Example 5-4**

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

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

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

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

5.3.3.1.3 Existence of Subordinated Debt

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

**Example 5-5**

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

In a qualitative assessment, the existence of subordinated debt is a factor indicating that D does not have sufficient equity at risk. That factor should be considered along with all other facts and circumstances (e.g., a 50 percent ratio of equity at risk frequently exceeds expected losses). If the qualitative assessment is inconclusive, a quantitative analysis (i.e., calculation of expected losses/residual returns) should be performed to determine whether D is a VIE.
Example 5-5 (continued)

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

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

5.3.3.1.4 Development-Stage Entities

Since life sciences entities frequently require varying levels of funding to complete a product candidate’s R&D, it is important for such entities to understand the “sufficiency of the equity investment at risk” characteristic in the VIE analysis when evaluating the funding of each R&D phase.

Before the adoption of ASU 2014-10, certain entities could qualify for specialized accounting under ASC 915 as development-stage entities. Such entities were, by definition, in a stage of development as opposed to conducting operations in accordance with their principal plan. Accordingly, those qualifying entities differed in nature from other entities, often being capitalized only to the extent required to perform a specific task related to development.

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

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

This framework was more generous than the approach applicable to entities that did not qualify as development-stage entities since it took into account the life cycle of the legal entity in phases rather than over the entire contemplated life of the legal entity. This specialized approach applied only to the sufficiency of equity investment at risk; an assessment of the other conditions of a VIE still needed to be performed for such legal entities.

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5 ASU 2014-10 eliminated the specialized approach for considering sufficiency of equity investment at risk for development-stage entities. That ASU became effective for PBEs for annual periods beginning after December 15, 2015, and interim periods therein. For entities other than PBEs, the guidance became effective for annual periods beginning after December 15, 2016, and interim periods beginning after December 15, 2017. As a result of these effective dates and early adoption, virtually all entities have adopted the ASU. Reporting entities that have historically applied this exception should consider the impact of ASU 2014-10 on their historical conclusions.
Under this framework, a reporting entity (1) initially assessed whether a development-stage entity was a VIE on the date the reporting entity first became involved with the legal entity and (2) reconsidered its assessment upon the occurrence of any of the events described in ASC 810-10-35-4. For a development-stage entity, such events would include, but not be limited to:

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

Although ASU 2014-10 removed the concept of a development-stage entity, we believe that it is still necessary to consider the design of a legal entity in the determination of whether the legal entity’s equity investment at risk is sufficient. That is, for certain legal entities that met the definition of a development-stage entity under previous guidance, considering only the legal entity’s current stage of development may be appropriate in the assessment of sufficiency of equity. Specifically, if a legal entity is in the development stage and there is substantial uncertainty about whether the legal entity will proceed to the next stage, it may be appropriate to consider only the current stage in the sufficiency assessment. This approach is consistent with the assessment of power in the primary-beneficiary analysis of a multiple-stage entity.

Example 5-6

Entity D is a development-stage entity. Investor A and Investor B each contributed $1 million of equity financing to D. Entity D’s current activities consist of product development and marketing surveys (“phase I”). Upon successful completion of phase I, D plans to commence test marketing (i.e., selling the products in selected areas) (“phase II”). During the final phase of D’s development stage, it plans to engage in limited-scale production and selling efforts (“phase III”). Entity D’s by-laws allow A and B to fund additional equity upon the completion of phase I and phase II. However, it is not certain that D will proceed to phase II.

In the assessment of whether D has sufficient equity at risk under ASC 810-10-15-14(a), only the current phase of D’s development needs to be considered. Thus, if, at inception, the $2 million of equity capital is deemed sufficient to finance phase I, D would be considered to have sufficient equity investment at risk. This determination should be reassessed at the commencement of phase II and phase III, upon the funding of additional equity financing, or upon the occurrence of any of the events in ASC 810-10-35-4.

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

The manner in which a reporting entity determines whether it holds a controlling financial interest in a legal entity under the VIE model is different from how it makes the determination under the voting interest entity model. The voting interest entity model focuses on the voting rights conveyed by equity interests. Since the holder of an interest other than equity may control the legal entity, the voting interest entity model may not yield an appropriate consolidation conclusion if the equity interests collectively do not possess the characteristics that are typical of equity interests. Accordingly, a legal entity is considered a VIE if the at-risk holders as a group, through their equity investment at risk, lack any of the following three qualities, which are the “typical” characteristics of an equity investment:

- The power to direct the most significant activities of the legal entity.
- The obligation to absorb the expected losses of the legal entity.
- The right to receive the expected residual returns of the legal entity.
The rights of the equity investment at risk investor group must be a characteristic of the equity investment at risk itself and not a characteristic of other interests held by the current holders of the equity investment at risk. It is not necessary for each individual equity investment at risk to possess all three characteristics, but the total equity investment at risk must possess them all. By implication, as long as the group of at-risk equity investors possesses these three characteristics through their equity investment at risk, the failure of any one at-risk equity investor to possess the characteristics would not make the legal entity a VIE.

Example 5-7

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

5.3.3.3 Disproportionate (Nonsubstantive) Voting Rights

Although intended to clarify the previous criteria (at-risk equity investors as a group do not possess characteristics of a controlling financial interest), the evaluation of whether disproportionate (nonsubstantive) voting rights exist is generally considered a separate condition in the assessment of a VIE. ASC 810-10-15-14(c)(2) explains that the provision “is necessary to prevent a primary beneficiary from avoiding consolidation of a VIE by organizing the legal entity with nonsubstantive voting interests.” Thus, ASC 810-10-15-14(c) is referred to as the “anti-abuse provision” since it aims to prevent a legal entity from being structured in a manner such that the legal entity does not confer voting control to a reporting entity but in substance should be consolidated by the reporting entity because “substantially all” of the legal entity’s activities either involve the reporting entity or are conducted on the reporting entity’s behalf. See Section 5.4 of Deloitte’s Consolidation Roadmap for more interpretive guidance on evaluating this criterion.

5.3.3.4 SEC Comment Letters Related to the Determination of Whether a Legal Entity Is a VIE

Example of an SEC Comment

We note from your prior response that you believe you should consolidate [the legal entity] under either the variable interest or voting interest models. Please tell us how you considered ASC 810-10-15-14 in determining whether [the legal entity] has the characteristics of a variable interest entity.

Given that the variable interest model is complex and requires an entity to use significant judgment, the SEC staff frequently requests further information from registrants about how they concluded that an entity either is or is not a VIE.

5.3.4 Identifying the Primary Beneficiary of a VIE

The primary beneficiary of a VIE is the party required to consolidate the VIE (i.e., the party with a controlling financial interest in the VIE). Specifically, ASC 810-10-25-38A requires the reporting entity to perform an assessment that focuses on whether the reporting entity has both “power” and “economics.” These two concepts are discussed below. For more detailed information, see Chapter 7 of Deloitte’s Consolidation Roadmap.
5.3.4.1 Power Criterion

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

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

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

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

5.3.4.1.1 Contingencies

Future power can be conveyed to a variable interest holder upon the occurrence of a contingent event. Questions have arisen about whether such a variable interest holder can be the primary beneficiary of the VIE before the occurrence of that contingent event. When a party can direct activities only upon the occurrence of a contingent event, the determination of which party has power will require an assessment of whether the contingent event results in a change in power (i.e., power shifts from one party to another upon the occurrence of a contingent event) or whether the contingent event initiates the most significant activities of the VIE (i.e., the VIE’s most significant activities occur only when the contingent event happens).
Example 5-8

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

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

5.3.4.2 Economics Criterion

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

5.3.4.3 SEC Comment Letters Related to the Primary-Beneficiary Assessment

Example of an SEC Comment

Please describe to us the changes in the capital structure of [the legal entity] and in its contractual relationships with [you, as the reporting entity] that resulted in your conclusion that you are no longer its primary beneficiary and that you should deconsolidate [the legal entity] as of January 3, 2016. Explain to us in appropriate detail how these specific changes support your conclusion that you are no longer the primary beneficiary of the variable interest entity. Refer to the guidance provided in ASC 810-10, including ASC 810-10-35-4.

Because the primary-beneficiary assessment determines whether a registrant will consolidate an entity, the SEC staff will often request further information from registrants about their primary-beneficiary assessment.
5.3.5 Other Considerations

Example of an SEC Comment

We note you consolidate entities in which you have a variable interest and of which you are the primary beneficiary. Please tell us what consideration you gave to disclosing the information required by ASC 810-10-50-2AA regarding your involvement with variable interest entities, the information required by ASC 810-10-50-3 with respect to variable interest entities you consolidate as the primary beneficiary and the information required by ASC 810-10-50-4 with respect to variable interest entities you do not consolidate because you are not the primary beneficiary.

All reporting entities that have a variable interest in a VIE are subject to the disclosure requirements of ASC 810-10. Reporting entities should consider the overall objectives of ASC 810-10-50-2AA and, depending on the circumstances, may need to supplement their disclosures to meet these objectives. Meeting the disclosure requirements can sometimes be challenging because a reporting entity might not be privy to all the information about a VIE, especially if the reporting entity is not the primary beneficiary of the VIE but has a variable interest in the VIE and is subject to some of the VIE’s disclosure requirements. Given the nature of variable interests often held by life sciences entities in VIEs, it is important for life sciences entities to keep these disclosure requirements in mind when preparing financial statements.

Because this publication is intended to highlight some of the complex issues frequently encountered by life sciences entities, certain consolidation topics are outside its scope. However, such topics are discussed in Deloitte’s Consolidation Roadmap; they include, but are not limited to, (1) the assessment of related parties in the identification of variable interests and performance of the primary-beneficiary analyses, (2) consolidation evaluations involving voting interest entities, and (3) special considerations related to limited partnerships and similar entities.

Further, for additional discussion of R&D funding arrangements that involve legal entities, see Section 3.2.1.

5.4 Targeted Improvements to the Related-Party Guidance for VIEs (ASU 2018-07)

In October 2018, the FASB issued ASU 2018-17, which amends two aspects of the related-party guidance in ASC 810. The ASU (1) adds an elective private-company scope exception to the VIE guidance for entities under common control and (2) removes a sentence in ASC 810-10-55-37D regarding the evaluation of fees paid to decision makers to conform with the amendments in ASU 2016-17.

5.4.1 Private-Company Scope Exception to the VIE Guidance for Certain Entities

ASU 2018-17 broadens the existing accounting alternative available to private companies by allowing all legal entities under common control to elect not to apply the VIE guidance as long as the reporting entity, the common-control parent, and the legal entity being evaluated for consolidation are not PBES and meet the criteria in ASC 810-10-15-17AD (added by the ASU). ASC 810-10-15-17AD states, in part:

A legal entity need not be evaluated by a private company (reporting entity) under the guidance in the Variable Interest Entities Subsections if all of the following criteria are met:

a. The reporting entity and the legal entity are under common control.

b. The reporting entity and the legal entity are not under common control of a public business entity.
c. The legal entity under common control is not a public business entity.

d. The reporting entity does not directly or indirectly have a controlling financial interest in the legal entity when considering the General Subsections of this Topic. The Variable Interest Entities Subsections shall not be applied when making this determination.

ASC 810-10-15-17AE (added by the ASU) provides guidance on applying criterion (a) above and establishes that solely for the purpose of applying criterion (a), a private-company reporting entity should consider only the voting interest model when determining whether the reporting entity and the legal entity are under common control. That is, a private-company reporting entity is not required to consider the VIE guidance when determining whether criterion (a) is met.

5.4.2 Evaluation of Fees Paid to a Decision Maker

ASU 2018-17 also removes a sentence from ASC 810-10-55-37D to conform the guidance on the consideration of indirect interests held by related parties under common control in the variable interest analysis with the guidance on the consideration of those interests in the primary-beneficiary analysis. Under the amended guidance, such indirect interests should be considered on a proportionate basis rather than considered in their entirety.

5.4.3 Effective Date and Transition

For entities other than private companies, ASU 2018-17 is effective for fiscal years beginning after December 15, 2019, including interim periods therein. For private companies, the ASU is effective for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. Early adoption is permitted. Entities are required to apply the ASU’s amendments retrospectively with a cumulative-effect adjustment to retained earnings at the beginning of the earliest period presented.

For more information about ASU 2018-17, see Deloitte’s November 19, 2018, Heads Up.

5.5 On the Horizon — Proposed ASU on Reorganizing the Consolidation Guidance

In September 2017, the FASB issued a proposed ASU that would reorganize the consolidation guidance in ASC 810 by creating a new Codification topic, ASC 812, with separate subtopics for the guidance on (1) the VIE model and (2) the voting interest entity model. The proposed ASU states that its goal is to make “navigating and understanding consolidation guidance easier without affecting how consolidation analyses are currently performed.” For additional information, see Deloitte’s October 5, 2017, Heads Up.

In June 2018, the FASB met to discuss comment letter feedback on the proposed ASU and decided to continue its existing project on reorganizing ASC 810. In addition, as stated in the FASB’s tentative Board decisions, the Board instructed its staff “to develop nonauthoritative educational material to address the more difficult parts of consolidation guidance with the goal of supporting and supplementing the reorganized authoritative consolidation guidance.”
6.1 Introduction

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

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

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

ASC 450 defines a loss contingency as an “existing condition, situation, or set of circumstances involving uncertainty as to possible loss to an entity that will ultimately be resolved when one or more future events occur or fail to occur.” Accrual of an estimated loss contingency through a charge against earnings is required if it is probable that an asset has been impaired or a liability has been incurred as of the date of the financial statements and the amount of the loss can be reasonably estimated. If the estimated amount of loss is within a range of amounts, and some amount within the range of loss appears to be a better estimate than any other amount within the range, entities must accrue that amount. If no amount within the range of loss is a better estimate than any other amount, entities must accrue the minimum amount within that range of loss. Disclosure of the nature of the accrued loss...
and, in some circumstances, the amount accrued may be required so that the financial statements are not misleading. With respect to unrecognized loss contingencies, ASC 450-20-50-3 and 50-4 note the following:

<table>
<thead>
<tr>
<th>ASC 450-20</th>
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<tr>
<td><strong>50-3</strong> Disclosure of the contingency shall be made if there is at least a reasonable possibility that a loss or an additional loss may have been incurred and either of the following conditions exists:</td>
</tr>
<tr>
<td>a. An accrual is not made for a loss contingency because any of the conditions in paragraph 450-20-25-2 are not met.</td>
</tr>
<tr>
<td>b. An exposure to loss exists in excess of the amount accrued pursuant to the provisions of paragraph 450-20-30-1.</td>
</tr>
<tr>
<td>Examples 1–3 (see paragraphs 450-20-55-18 through 55-37) illustrate the application of these disclosure standards.</td>
</tr>
<tr>
<td><strong>50-4</strong> The disclosure in the preceding paragraph shall include both of the following:</td>
</tr>
<tr>
<td>a. The nature of the contingency</td>
</tr>
<tr>
<td>b. An estimate of the possible loss or range of loss or a statement that such an estimate cannot be made.</td>
</tr>
</tbody>
</table>

A gain contingency arises if the outcome of future events may result in a possible gain or benefit to an entity (e.g., pending litigation whose outcome would result in a benefit). Unlike a loss contingency, a gain contingency is usually not reflected in the financial statements and should not be recorded in the financial statements before the contingency is realized. However, as stated in ASC 450-30-50-1, “[a]dequate disclosure shall be made of a contingency that might result in a gain, but care shall be exercised to avoid misleading implications as to the likelihood of realization.”

### 6.2 Industry Issues

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

**Q&A 6-1 Product Recalls**

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

**Question**

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

**Answer**

When the guidance in ASC 450-20 is applied to product recalls, the obligating event triggering liability recognition is the announcement of a recall. Except as provided for in a warranty arrangement, an entity has no legal obligation or duty associated with product design or manufacturing defects after the product is sold. Because there is no legal obligation, there is no event that gives rise to a probable loss until a recall is announced voluntarily or is mandated by regulators.
Q&A 6-2  Offers to Settle Litigation

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

**Question**

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

**Answer**

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

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

**Example**

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

The offer to settle is evidence that it is probable that a liability has been incurred as of the date of the financial statements and that the amount of the loss can be reasonably estimated. Company X should consider the guidance in ASC 450-20-30-1 in determining the appropriate amount to accrue. The amount of the offer establishes the low end of the range. If this amount is accrued, X must also disclose any additional exposure to loss in its financial statements if the disclosure requirements in ASC 450-20-50-3 are met.
Connecting the Dots
An entity should carefully consider all facts and circumstances when assessing whether an “offer” has been extended to settle litigation. For example, when the offer hinges on a counterparty's performance of certain actions to which the entity believes the counterparty is not likely to agree, the entity may conclude that an offer has not been extended.

Q&A 6-3 Accounting for Litigation Settlements When One or More Elements Exist
While some legal settlements in the life sciences industry involve only a single element (e.g., a claim or lawsuit over patent infringement), challenges often arise when a litigation settlement contains multiple elements.

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

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

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

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

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

Assume a company pays cash and conveys licenses to a plaintiff in order to settle a patent infringement and misappropriation of trade secrets claim. In exchange for the payment and licenses given, the company receives a promise to drop the patent infringement lawsuit, a covenant not to sue with respect to the misappropriation of trade secrets claim, and a license to use the patents subject to the litigation.
In this arrangement, the items given include cash and licenses, and the items received include the promise to drop the patent infringement lawsuit, the covenant not to sue, and the license to use the patents. After identifying these items and determining whether to recognize them, the company must use the relative fair value method or another approach (e.g., the residual value approach if one of the elements cannot be valued) to determine the proper allocation of consideration among the recognizable elements. Mr. West further clarified:

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

Connecting the Dots

In addition to determining the allocation of consideration to the recognized elements, life sciences entities are also encouraged to consider the appropriate classification of litigation settlements within their income statement, particularly when the plaintiff is a customer of the entity. As noted in Mr. West’s speech:

In the fact pattern that I’ve talked about so far it would be appropriate to record the consideration allocated to the litigation within operating expenses since the company did not have a prior relationship with the plaintiff. However, we believe that a different answer may result if the plaintiff is also a customer of the defendant. Assume a company settles a claim for over billing its customers for an amount that is in excess of the amounts they over billed. The company believed that the excess payment was necessary to preserve the customer relationship and had induced the customer to settle the claim. In this case we do not believe that classification of the entire payment as a settlement expense would be consistent with existing GAAP. Since the settlement payment was made to the company’s customers, we believe that the payment is within the scope of EITF [Issue] 01-9. As you may know, this EITF [Issue] addresses the accounting for consideration given by a vendor to a customer. The scope is broadly written and includes all consideration given by a vendor to a customer. It also requires that cash consideration paid be classified as a reduction of revenues unless the vendor receives an identifiable benefit and the fair value of that benefit can be reliably measured. In this fact pattern, we believe that the excess amount paid to the customer represents both a payment to retain the customer and settle the litigation. However, if the company is unable to determine the fair value of each of these components, we believe that EITF [Issue] 01-9 requires the entire payment to be classified as a reduction of revenues. Had the company been able to directly value the litigation, classification of that portion of the settlement payment as an expense may have been appropriate. [Footnote omitted]

In certain circumstances, life sciences entities may need to exercise significant judgment in determining whether a litigation settlement involves a customer. For example, when the plaintiff is a governmental entity and the life sciences entity participates in governmental programs (e.g., Medicare or Medicaid), the life sciences entity (1) should consider whether the payment made to the governmental entity represents a payment made to a customer and (2) is encouraged to document its judgments related to income statement classification of the settlement contemporaneously.
Q&A 6-4  Accounting for Liabilities When Demand for Payment Is Not Probable, and Whether Legally or Contractually Required Liabilities Can Be Derecognized on the Basis of a Probability Assessment

In the life sciences industry, obligations to a third party, such as a customer or patent holder, may arise as a result of a law or contract that may be unknown to the third party. Such obligations (e.g., a royalty liability required by contract for the use of a patent) should not be accounted for as loss contingencies under ASC 450-20 even if the third party is unaware of the obligation and is unlikely to demand payment. Further, if an entity believes that a liability for which payment is required by law or contract will ultimately be settled for less than the stated legal obligation, the entity should not derecognize the liability (or a portion of the liability) until the liability has been extinguished in accordance with ASC 405-20-40-1.

Question 1
Is a liability for which payment is required by law or contract a loss contingency accounted for under ASC 450-20 if it is uncertain whether the creditor is aware of the obligation and will demand payment?

Answer
No. In general, the probability of payment is irrelevant if settlement of the liability is required by law or contract. That is, other than deferred revenues, liabilities established by law or contract should be recorded at their stated amounts unless there is guidance under U.S. GAAP that requires otherwise.

Paragraph 36 of FASB Concepts Statement 6 states that a liability has the following three essential characteristics:

• “[I]t embodies a present duty or responsibility to one or more other entities that entails settlement by probable future transfer or use of assets at a specified or determinable date, on occurrence of a specified event, or on demand.”

• “[T]he duty or responsibility obligates a particular entity, leaving it little or no discretion to avoid the future sacrifice.”

• “[T]he transaction or other event obligating the entity has already happened.”

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

When the obligating event has occurred, the probability of payment is irrelevant to the determination of whether a contractual or legal obligation is a liability or a loss contingency. That is, when the obligating event has occurred, the entity has incurred a liability; accordingly, there is no contingency. This conclusion is supported by analogy to paragraph B21 of FASB Interpretation 48 (superseded), which states that the Board “also considered the guidance in paragraphs 26 and 36 of Concepts Statement 6 on the characteristics of an asset and a liability” and “noted that consideration of examination risk is not consistent with the characteristics of an asset or a liability.”
In this context, “examination risk” represents the risk that a taxing authority would examine a particular tax position. In the Background Information and Basis for Conclusions of FASB Interpretation 48, the Board rejected the idea that accounts payable, for example, should be recorded on the basis of the amount that an entity would ultimately pay if the creditor filed suit to collect the liability.

This conclusion is further supported by analogy to ASC 410-20-25-15, which states that an “unambiguous requirement that gives rise to an asset retirement obligation coupled with a low likelihood of required performance still requires recognition of a liability.”

In addition, a liability is not an unasserted claim or assessment under ASC 450-20 if the satisfaction of the liability is required by law or contract. The existence of the law or the contract constitutes an assertion of the claim. This conclusion is supported by analogy to paragraph B20 of FASB Interpretation 48, which states that the “Board considered the guidance on unasserted claims in paragraph 38 of Statement 5 [codified in ASC 450-20-55-14 and 55-15]” and “does not believe that guidance is applicable to tax positions because a tax return is generally required to be filed based on the provisions of tax law.”

**Question 2**

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

**Answer**

No. ASC 405-20-40-1 states the following (pending content effective upon adoption of ASU 2016-04 {in braces}):

(Unless addressed by other guidance (for example, paragraphs 405-20-40-3 through 40-4 or paragraphs 606-10-55-46 through 55-49), a) A debtor shall derecognize a liability if and only if it has been extinguished. A liability has been extinguished if either of the following conditions is met:

a. The debtor pays the creditor and is relieved of its obligation for the liability. Paying the creditor includes the following:
   1. Delivery of cash
   2. Delivery of other financial assets
   3. Delivery of goods or services
   4. Reacquisition by the debtor of its outstanding debt securities whether the securities are cancelled or held as so-called treasury bonds.

b. The debtor is legally released from being the primary obligor under the liability, either judicially or by the creditor. For purposes of applying this Subtopic, a sale and related assumption effectively accomplish a legal release if nonrecourse debt (such as certain mortgage loans) is assumed by a third party in conjunction with the sale of an asset that serves as sole collateral for that debt.
Example

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

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

The contract requires Y to make royalty payments on the basis of sales volume. Therefore, Y is under an obligation to the patent holder as the equipment is sold (i.e., Y has a present duty to the patent holder). Company Y’s uncertainty about whether a patent holder will audit the sales volume does not allow it to avoid future payment. However, Y should not record a royalty liability for future sales until those sales actually occur. Further, if a patent holder cannot be located, the contractual liability should not be reduced until the liability derecognition guidance in ASC 405-20-40-1 has been met, which could be when the escheat laws for the particular jurisdiction are complied with and the obligation no longer exists.

Q&A 6-5  Events Occurring After the Date of the Financial Statements

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

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

Question

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

Answer

No. The enactment of a law after the balance sheet date but before issuance of the financial statements would be accounted for as a nonrecognized subsequent event (because the newly enacted law does not provide evidence about conditions that existed as of the balance sheet date). The entity should consider whether it is required to disclose the event to keep the financial statements from being misleading.
Example

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

Q&A 6-6 Favorable Legal Settlements

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

Question

Upon the receipt of a favorable verdict in a court case, is recognition of a gain contingency appropriate?

Answer

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

Example

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

The SEC staff continues to closely monitor SEC registrants' contingency disclosures, and it comments when such disclosures do not comply with U.S. GAAP or SEC rules and regulations.

The staff has continued to comment on:

- Lack of specificity regarding the nature of the matter.
- Lack of quantification of amounts accrued, if any, and possible loss or range of loss (or disclosure about why such an estimate cannot be made).
- Lack of disclosure or insufficient detail about what triggered a significant current-period accrual for a contingency when no loss or a significantly lower amount was accrued in prior periods (i.e., the lack of “early warning” disclosures in prior periods).
- Insufficient detail about judgments and assumptions underlying significant accruals.
- Insufficient detail about (and untimely reporting of) new developments related to loss contingencies and the effect of such developments on current and future periods.
- Inconsistency among disclosures in the footnotes, in other sections of the filing (e.g., risk factors and legal proceedings), and outside the filing (e.g., in press releases and earnings calls). In addition, if different registrants are parties to a claim, the SEC staff may also review the counterparty's filings and comment if the information is not consistent.
- Use of unclear language in disclosures (e.g., not using terms that are consistent with accounting literature, such as “probable” or “reasonably possible”) and failure to consider the disclosure requirements in ASC 450, SAB Topic 5.Y, and SEC Regulation S-K, Item 103.
- Lack of disclosure of an accounting policy related to accounting for legal costs (when material) and uncertainties in loss contingency recoveries, including (1) whether ranges of reasonably possible losses are disclosed gross or net of anticipated recoveries from third parties, (2) risks regarding the collectibility of anticipated recoveries, and (3) the accounting policy for uncertain recoveries.

Below are examples of certain SEC staff comments that registrants in the life sciences industry and other industries have received regarding their accounting for contingencies. For more information about SEC comment letter themes that pertain to the life sciences industry, see Deloitte’s A Roadmap to SEC Comment Letter Considerations, Including Industry Insights.

6.3.1 Loss Contingencies

Examples of SEC Comments

- With respect to the cyber-security incident and related assessments and litigation, please tell us your consideration of the requirement in ASC 450-20-50-4.b. to disclose an estimate of the possible loss or range of loss or to disclose that such an estimate cannot be made.
- We note that you have evaluated your potential exposure related to [Matter A] and have established a loss contingency of $[X] to cover your probable and estimable liabilities as of September 30, 2016. If there is at least a reasonable possibility that a loss exists in excess of the amount accrued, please revise to either disclose an estimate (or, if true, state that the estimate is immaterial in lieu of providing quantified amounts) of the additional loss or range of loss or state that such an estimate cannot be made. Please refer to ASC 450-20-50-3 to 4 and include your proposed disclosures in your response.
The SEC staff often asks about estimates of reasonably possible losses or comments when a registrant omits disclosure of a loss or range of losses because its estimates lack “precision and confidence.” If an estimate of the loss or range of losses cannot be made, the staff expects registrants to (1) disclose, in accordance with ASC 450-20-50-4, that such an estimate cannot be made and (2) demonstrate that they at least attempted to estimate the loss or range of losses before concluding that an estimate cannot be made. In such cases, the staff has commented that registrants should disclose the specific factors that limited their ability to reasonably estimate the loss or range of losses and has asked about registrants' quarterly procedures related to such estimates. The factors disclosed should be specific to the loss contingency in question and could include representations that (1) claims do not specify an amount of damages, (2) there are a large number of plaintiffs, or (3) the case is in its early stages.

Further, if a registrant discusses a potential contingency in its earnings calls, the SEC staff is likely to seek more information about the contingency and to inquire about whether the related disclosures are appropriate. The staff encourages registrants to clearly disclose the “full story” regarding their loss contingencies because recognition of such contingencies requires a high degree of professional judgment. Further, the staff has noted that disclosures related to loss contingencies should be continually evaluated over time as facts and circumstances change.

The SEC staff may also ask about (1) the basis for a registrant's accrual (e.g., factors supporting an accrual, such as trends in claims received and rejected), (2) the timing of a loss contingency's recognition, and (3) the disclosure of a loss contingency. In addition, when a material settlement is disclosed during the period, the staff may review prior-period disclosures to determine whether such disclosures were appropriate (i.e., whether the registrant should have provided early-warning disclosures about the possibility of incurring or settling a loss in future periods to help users understand these risks and how they could potentially affect the financial statements) or whether an accrual should have been recognized in a prior period.

### 6.3.2 Litigation Contingencies

In addition to complying with ASC 450, public entities must separately meet the requirements of SEC Regulation S-K, Item 103, when disclosing litigation matters because while those requirements are similar to the requirements of ASC 450, they are not identical. Also, to address concerns related to a registrant's contention that providing too much information may be detrimental to efforts to litigate or settle matters, the SEC staff has indicated that registrants do not need to separately disclose each asserted claim; rather, they may aggregate asserted claims in a logical manner as long as the disclosure complies withASC 450.
Chapter 7 — Statement of Cash Flows

7.1 Introduction
While the accounting principles underlying the statement of cash flows have been in place for many years, challenges in interpretation and preparation have consistently made the statement of cash flows one of the leading causes of restatements and comments from the SEC staff for life sciences entities. In Section 7.2 below, we highlight issues commonly encountered by life sciences entities that are associated with the classification of cash flows as operating, investing, or financing. For more information as well as insights into topics not addressed below, see Deloitte’s *A Roadmap to the Preparation of the Statement of Cash Flows*.

7.2 Industry Issues

7.2.1 Foreign Currency Cash Flows
The global nature of life sciences entities often gives rise to transactions that are denominated in a foreign currency and to businesses that operate in foreign functional currency environments. For example, the product supply chain structure for many life sciences entities involves the movement of materials and products across international borders throughout the manufacturing life cycle, giving rise to many transactions that are exposed to changes in the exchange rate.

An entity should report the cash flow effect of transactions denominated in a foreign currency by using the exchange rates in effect on the date of such cash flows. Instead of using the actual exchange rate on the date of a foreign currency transaction, an entity may use an average exchange rate for translation if the exchange rates are relatively consistent throughout the reporting period.

An entity with operations whose functional currency is the foreign currency may use the following approach when preparing its consolidated statement of cash flows:

- Prepare a separate statement of cash flows for each foreign operation by using the operation’s functional currency.
- Translate the stand-alone cash flow statement prepared in the functional currency of each foreign operation into the reporting currency of the reporting entity.
- Consolidate the individual translated statements of cash flows.

The effects of exchange rate changes, or translation gains and losses, are not the same as the effects of transaction gains and losses and should not be presented or calculated in the same manner.

Effects of exchange rate changes may directly affect cash receipts and payments but do not directly result in cash flows themselves.
Because unrealized transaction gains and losses arising from the remeasurement of foreign-currency-denominated monetary assets and liabilities on the balance sheet date are included in the determination of net income, such amounts should be presented as a reconciling item between net income and net cash from operating activities (either on the face of the statement under the indirect method or in a separate schedule under the direct method). Subsequently, any cash flows arising from the settlement of the foreign-currency-denominated asset and liability should be presented in the statement of cash flows as an operating, investing, or financing activity on the basis of the nature of such cash flows.

Translation gains and losses, however, are recognized in other comprehensive income and are not included in the cash flows from operating, investing, or financing activities.

The effects of exchange rate changes on cash should be shown as a separate line item in the statement of cash flows as part of the reconciliation of beginning and ending cash balances.

In a manner consistent with the implementation guidance in ASC 830-230-55-15, the effect of exchange rate changes on cash and cash equivalents is the sum of the following two components:

- For each foreign operation, the difference between the exchange rates used in translating functional currency cash flows and the exchange rate at year-end multiplied by the net cash flow activity for the period measured in the functional currency.
- The fluctuation in the exchange rates from the beginning of the year to the end of the year multiplied by the beginning cash balance denominated in currencies other than the reporting currency.

### 7.2.2 Transactions Associated With Acquisitions

The life sciences industry continues to experience significant M&A activity, and transactions associated with acquisitions affect a company’s statement of cash flows in a number of ways.

#### 7.2.2.1 Presentation of Acquisition-Related Costs

When consummating a business combination, an acquirer frequently incurs acquisition-related costs such as advisory, legal, accounting, valuation, and professional and consulting fees. Except for certain debt and equity issuance costs, ASC 805 requires that an entity expense all such acquisition-related costs as incurred. The costs of issuing debt or equity securities as part of a business combination are recognized in accordance with other applicable accounting literature.

In the deliberations before the issuance of Statement 141(R) (codified in ASC 805), the FASB determined that acquisition-related costs are not considered part of the fair value exchange between the buyer and seller of the business; rather, they are separate transactions in which the buyer pays for services that it receives. Further, the definition of operating activities in the ASC master glossary states, in part, that “[c]ash flows from operating activities are generally the cash effects of transactions and other events that enter into the determination of net income.” Because acquisition-related costs accounted for under ASC 805 are expensed and affect net income, these costs should be reflected as operating cash outflows in the statement of cash flows.
7.2.2.2 Debt in a Business Combination

The classification in the statement of cash flows of cash paid to settle acquiree debt in a business combination should be consistent with the acquirer's treatment of the debt in acquisition accounting (i.e., whether the debt was treated as a liability assumed in acquisition accounting). If the acquirer legally assumes the acquiree's debt as part of the business combination, the acquirer will generally present the extinguishment as a financing activity (in a manner consistent with how it would present the repayment of a debt obligation outside of a business combination). Conversely, if the acquirer does not legally assume the acquiree's debt as part of the business combination that was subsequently extinguished, the acquirer will generally present the extinguishment as an investing activity (in a manner consistent with how it would present cash consideration paid in a business combination).

Example 7-1

Company P has entered into a credit agreement with Bank A for unsecured senior notes (the “Notes”). The provisions of the credit agreement require that the Notes be repaid upon a change-of-control event. On March 31, 20X4, Company B acquires P for cash consideration and accounts for the acquisition as a business combination. Before B's consummation of the business combination, P notifies A that a change-of-control event will occur in connection with B's acquisition of P and that the Notes will be repaid simultaneously with the business combination. Further, B determines that it did not legally assume the Notes and therefore did not account for the Notes as a liability assumed in acquisition accounting. Because B did not legally assume the Notes as part of the acquisition and did not account for the Notes as liabilities assumed in acquisition accounting, B should present the cash consideration paid for the extinguishment of the Notes as an investing outflow in its statement of cash flows.

7.2.2.3 Contingent Consideration Classified as a Liability

It is common in business combinations entered into by life sciences companies for a portion of the consideration to be contingent on future events. ASC 805 requires the acquirer to recognize the acquisition-date fair value of the contingent consideration arrangement as part of the consideration transferred in exchange for the acquiree. The contingent consideration arrangement is classified either as a liability or as equity in accordance with applicable U.S. GAAP. In transactions involving life sciences companies, contingent consideration is frequently classified as a liability.

As discussed in the Section 7.3, the FASB issued ASU 2016-15 in August 2016. The ASU amends the guidance in ASC 230-10-45-13, ASC 230-10-45-15, and ASC 230-10-45-17 and requires that entities determine the classification of payments to settle a contingent consideration liability (after the acquisition date in a business combination transaction) on the basis of when such payments are made. Under the ASU, classification of the payments depends, in effect, on whether they are made soon after the acquisition in a business combination transaction. That is, cash payments not made soon after the acquisition — up to the amount of the contingent consideration liability, including any measurement-period adjustments and less any amounts paid soon after the acquisition date to settle the contingent consideration liability — will be classified in financing activities; any excess cash payments will be classified in operating activities. Cash payments made soon after the acquisition date in a business combination transaction will be classified in investing activities. While the guidance does not define the term "soon after," we generally believe that payments made within three months after the acquisition date would qualify for classification in investing activities. This view is consistent with paragraph BC16 of ASU 2016-15, which states that “some [Emerging Issues] Task Force members believe that a payment for contingent consideration that was made soon after a business combination is an extension of the cash paid for the business acquisition (an investing activity), if that payment for contingent consideration was made within a relatively short period of time after the acquisition date (for example, three months or less).”
7.2.2.4 Acquired IPR&D Assets With No Alternative Future Use

The acquisition of IPR&D assets as part of either a business combination or an asset acquisition is common in the life sciences industry. In accordance with ASC 730, IPR&D assets acquired as part of an asset acquisition rather than as part of a business combination should be expensed as of the acquisition date unless such assets have an alternative future use, in which case such assets should be capitalized. All IPR&D assets acquired as part of a business combination should initially be capitalized regardless of whether the assets have an alternative future use. See Chapter 4 for additional information.

We have observed diversity in practice in how cash payments for IPR&D assets acquired in an asset acquisition are reported in the statement of cash flows when such assets have no alternative future use. While some entities classify the cash payments in operating activities, other entities classify the cash payments in investing activities. Considerations related to such classification are discussed below.

7.2.2.4.1 Classification in Operating Activities

Classification in operating activities of cash outflows for IPR&D assets acquired in an asset acquisition that do not have an alternative future use is supported by the following:

- Such cash outflows are not specifically defined as investing or financing activities in ASC 230.
- Since such cash outflows are immediately expensed, they represent “the cash effects of transactions and other events that enter into the determination of net income” in a manner consistent with the definition of operating activities in the ASC master glossary.

7.2.2.4.2 Classification in Investing Activities

Classification in investing activities of cash outflows for IPR&D assets acquired in an asset acquisition that do not have an alternative future use is supported by the following Q&A in paragraph 5.12 of the AICPA Accounting and Valuation Guide Assets Acquired to Be Used in Research and Development Activities:

**Question 1**: How should an acquiring entity classify in its statement of cash flows an R&D charge associated with the costs of IPR&D projects acquired as part of an asset acquisition that have no alternative future use?

**Answer**: Best practices suggest that an acquiring entity should report its cash acquisition of assets to be used in R&D activities as an investing outflow in its statement of cash flows. In this regard, an acquiring entity should treat assets acquired to be used in R&D activities similar to how it reports other acquired assets in the statement of cash flows. Although acquired IPR&D may lack an alternative future use and, therefore, would be expensed immediately, it is still an asset for cash flow statement purposes.

When arriving at cash flows from operating activities under the indirect method of reporting cash flows, best practices suggest that an acquiring entity should add back to net income the costs of assets acquired to be used in R&D activities that are charged to expense. That adjustment is necessary to eliminate from operating cash flows those cash outflows of assets acquired to be used in R&D activities that are reflected in investing activities.

Treatment of the cash outflows as investing activities would align the cash flow reporting of IPR&D assets acquired as part of a business combination with that of IPR&D assets acquired as part of an asset acquisition.
7.2.2.4.3 **Accounting Policy Election**

Given the lack of authoritative guidance on this matter and the diversity in practice, we believe that classification in either operating or investing activities is acceptable. An entity's election is a matter of accounting policy that should be consistently applied to similar arrangements and disclosed if material.

7.2.3 **Stock Compensation**

The complexity of stock compensation arrangements often leads to additional presentation issues related to a life sciences entity's statement of cash flows. Two of the more common issues encountered by life sciences entities are addressed below.

7.2.3.1 **Settlement of Equity-Classified Share-Based Payment Awards**

When settling an equity-classified share-based payment award, an entity presents the settlement in its statement of cash flows on the basis of whether the amount paid to settle the award is greater than or less than the fair-value-based measure of the award on the settlement date:

- **Amount paid to settle the award does not exceed the fair-value-based measure of the award on the settlement date** — In accordance with ASC 718-20-35-7, if the cash paid to repurchase the equity-classified award does not exceed the fair-value-based measure of the award on the repurchase date, the cash paid to repurchase the award is charged to equity. That is, repurchase of the equity-classified award is viewed as reacquisition of the entity's equity instruments. Accordingly, the cash paid to reacquire the entity's equity instruments is presented as a cash outflow for financing activities under ASC 230-10-45-15(a), which indicates that payments of dividends or other distributions to owners, including outlays to reacquire the entity's equity instruments, are cash outflows for financing activities.

- **Amount paid to settle the award exceeds the fair-value-based measure of the award on the settlement date** — If the cash paid to repurchase the equity-classified award exceeds the fair-value-based measure of the award on the repurchase date, the cash paid in excess of the fair-value-based measure of the award is viewed as compensation for additional employee services and is recognized as additional compensation cost. Accordingly, if the equity-classified award is repurchased for an amount in excess of the fair-value-based measure, the portion of the cash paid to reacquire the entity's equity instruments that equals the fair-value-based measure of the award is presented as a cash outflow for financing activities under ASC 230-10-45-15(a). The portion of the cash paid in excess of the fair-value-based measure, for additional employee services, is presented as a cash outflow for operating activities under ASC 230-10-45-17(b), which notes that cash payments to employees for services are cash outflows for operating activities.

**Example 7-2**

Company A is making a tender offer to repurchase $20 million of common stock in the aggregate (the stock was originally distributed as share-based compensation awards) from its current employees. On the basis of an independent third-party valuation, A concludes that the purchase price paid to the employees for the common stock exceeds the fair value of the common stock by a total of $4.5 million. In accordance with ASC 718-20-35-7, the amount paid to employees up to the fair value of common stock acquired should be recognized in equity as a treasury stock transaction and should therefore be presented as a cash outflow for financing activities. The $4.5 million that was paid in excess of the fair value of the common stock constitutes compensation expense and is therefore presented as a cash outflow for operating activities.
7.2.3.2 Settlement of Liability-Classified Share-Based Payment Awards

In accordance with ASC 718-30, the grant-date fair-value-based measure and any subsequent changes in the fair-value-based measure of a liability-classified award through the date of settlement are recognized as compensation cost. Accordingly, the cash paid to settle the liability-classified award is effectively payment for employee services and is presented as a cash outflow for operating activities under ASC 230-10-45-17(b).

Note that an entity may enter into an agreement to repurchase (or offer to repurchase) an equity-classified award for cash. Depending on the facts and circumstances, the agreement to repurchase (or offer to repurchase) may be accounted for as either (1) a settlement of the equity-classified award or (2) a modification of the equity-classified award that changes the award's classification from equity to liability, followed by a settlement of the now liability-classified award.

If the agreement to repurchase (or offer to repurchase) is considered a settlement of an equity-classified award, the cash paid to reacquire the entity's equity instruments is presented in a manner consistent with the equity awards discussed in Section 7.2.3.1. If the agreement to repurchase (or offer to repurchase) is considered a modification of the equity-classified award that changes the award's classification from equity to liability, the cash paid to settle the liability-classified award should be presented in the statement of cash flows in a manner similar to the conclusion above. That is, under ASC 230-10-45-17(b), the cash paid to settle the liability-classified award is effectively payment for employee services and is presented as a cash outflow for operating activities.

7.2.4 Government Grants

Government grants are a form of government assistance that may be granted to PBEs or private companies to encourage those entities to fulfill certain objectives (e.g., providing a financial grant to an entity to fund cancer research). Generally, a recipient of a government grant is not expected to repay the grant provided that the recipient complies with the grant's conditions.

Not all government assistance is provided to a recipient in the form of a cash payment. For example, a government grant could be in the form of tax credits. In these situations, an entity must determine whether the tax credits are refundable.

Refundable tax credits (e.g., qualifying R&D credits in certain countries and state jurisdictions and alternative fuel tax credits for U.S. federal income tax) do not depend on an entity's ongoing tax status or tax position, allowing an entity to receive a refund despite being in a taxable loss position. Consequently, the refundable tax credits are similar to government grants and are generally accounted for similarly. The discussions below address such tax credits as well as other government grants. For more information on the accounting for refundable tax credits, see Section 2.04 of Deloitte’s A Roadmap to Accounting for Income Taxes.

7.2.4.1 Expenditures Incurred Before Receipt of a Grant

When an entity pays for capital expenditures or operating expenses before the reimbursement of government grant monies, it should present the receipt of the government grant in the statement of cash flows in a manner consistent with the presentation of the related cash outflow (as determined under ASC 230-10-45). For example, a government grant that is intended to reimburse an entity for qualifying operating expenses would be presented in the statement of cash flows as an operating activity if the grant was received after the operating expenses were incurred.
7.2.4.2 **Expenditures Incurred After Receipt of a Grant**

Receiving a grant before incurring the related expenditures is similar to an entity's receipt of a refundable loan advance or to an NFP's receipt of a contribution of refundable advance that by donor stipulation is restricted for capital investment. ASC 230-10-45-14(c) requires that the following be classified as cash inflows from financing activities:

Receipts from contributions and investment income that by donor stipulation are restricted for the purposes of acquiring, constructing, or improving property, plant, equipment, or other long-lived assets or establishing or increasing a donor-restricted endowment fund.

Therefore, when an entity receives the government grant before incurring the related capital expenditures or operating expenses, it should present the receipt of the government grant as a financing cash inflow in the statement of cash flows. In addition, when the entity incurs the expenditures in accordance with the conditions of the government grant, it should disclose the existence of a noncash financing activity resulting from the fulfillment of the grant requirements.

7.3 **New Accounting Standards**

7.3.1 **Classification of Certain Cash Receipts and Cash Payments**

In August 2016, the FASB issued **ASU 2016-15**, which amends ASC 230 to add or clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows. The ASU was the result of consensuses reached by the EITF to reduce the diversity in practice that has developed. Key provisions of the amendments are summarized below.

<table>
<thead>
<tr>
<th>Cash Flow Issues</th>
<th>Amendments</th>
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<tbody>
<tr>
<td>Debt prepayment or debt extinguishment costs</td>
<td>Cash payments for debt prepayment or extinguishment costs (including third-party costs, premiums paid, and other fees paid to lenders that are directly related to the debt prepayment or debt extinguishment, excluding accrued interest) must “be classified as cash outflows for financing activities.”</td>
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<tr>
<td>Settlement of zero-coupon bonds</td>
<td>The cash outflows for the settlement of a zero-coupon bond must be bifurcated into operating and financing activities. The portion of the cash payment related to accreted interest should be classified in operating activities, while the portion of the cash payment related to the original proceeds (i.e., the principal) should be classified in financing activities.</td>
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</table>
Contingent consideration payments made after a business combination

Contingent consideration payments that were not made soon after a business combination (on the basis of the consummation date) must be separated and classified in operating and financing activities. Cash payments up to the amount of the contingent consideration liability recognized as of the acquisition date, including any measurement-period adjustments, should be classified in financing activities, while any excess cash payments should be classified in operating activities.

For example, assume that Entity A acquired Entity B on December 31, 2016, for cash consideration of $100 million plus an earn-out provision with a maximum payout of $50 million payable on January 31, 2019. Entity A classified the contingent consideration as a liability and determined that the acquisition-date fair value was $20 million, for total consideration of $120 million. On the basis of the performance of B’s legacy operations, A determined that the fair value of the contingent consideration was $30 million on December 31, 2017, and $35 million on December 31, 2018.

Entity A should present information in its statement of cash flows as follows:

- **December 31, 2016** — Entity A should disclose a $100 million investing outflow related to the acquisition and a noncash investing activity of $20 million related to the contingent consideration portion of the acquisition.
- **December 31, 2017** — Entity A should disclose a $10 million reconciling item between net income and cash flows from operating activities related to the adjustment of the contingent consideration obligation.
- **December 31, 2018** — Entity A should disclose a $5 million reconciling item between net income and cash flows from operating activities related to the adjustment of the contingent consideration obligation.
- **January 31, 2019** — Of the $35 million A paid to the former owners of B, $20 million represents the portion recognized in purchase accounting and therefore should be classified as a financing activity. The remaining $15 million (i.e., the change in the liability after the acquisition date) should be reflected as a cash outflow for operating activities.

Proceeds from the settlement of insurance claims

Cash proceeds from the settlement of insurance claims should be classified on the basis of the nature of the loss. For insurance proceeds received in a lump-sum settlement, an entity should determine the classification on the basis of the nature of each loss included in the settlement.

Proceeds from the settlement of corporate-owned life insurance (COLI) policies and bank-owned life insurance (BOLI) policies

Cash proceeds from the settlement of COLI and BOLI policies must be classified in investing activities. However, an entity is permitted, but not required, to align the classification of premium payments on COLI and BOLI policies with the classification of COLI and BOLI proceeds (i.e., payments for premiums may be classified as investing, operating, or a combination thereof).

<table>
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<tr>
<td>Distributions received from equity method investees</td>
<td>An entity is required to make an accounting policy election to classify distributions received from equity method investees under either of the following methods:</td>
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<td>• <em>Cumulative-earnings approach</em> — Under this approach, distributions are presumed to be returns on investment and classified as operating cash inflows. However, if the cumulative distributions received, less distributions received in prior periods that were determined to be returns of investment, exceed the entity's cumulative equity in earnings, such excess is a return of capital and should be classified as cash inflows from investing activities.</td>
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<td>• <em>Nature of the distribution approach</em> — Under this approach, each distribution is evaluated on the basis of the source of the payment and classified as either operating cash inflows or investing cash inflows.</td>
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<td>If an entity whose chosen policy is the nature of the distribution approach cannot apply the approach because it does not have enough information to determine the appropriate classification (i.e., the source of the distribution), the entity must apply the cumulative-earnings approach and report a change in accounting principle on a retrospective basis. The entity is required to disclose that a change in accounting principle has occurred as a result of the lack of available information as well as the information required under ASC 250-10-50-2, as applicable.</td>
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<td>The amendments do not address equity method investments measured under the fair value option.</td>
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<tr>
<td>Beneficial interests in securitization transactions</td>
<td>A transferor's beneficial interests received as proceeds from the securitization of an entity's financial assets must be disclosed as a noncash activity. Subsequent cash receipts of beneficial interests from the securitization of an entity's trade receivables must be classified as cash inflows from investing activities.</td>
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</table>

In addition to the specific transaction guidance discussed above, ASU 2016-15 provides a three-step approach for classifying cash receipts and payments that have aspects of more than one class of cash flows:

1. An entity should first apply specific guidance in U.S. GAAP, if applicable.
2. If there is no specific guidance related to the cash receipt or payment, an entity should bifurcate the cash payment or receipt into “each separately identifiable source or use [of cash] on the basis of the nature of the underlying cash flows.” Each separately identifiable source or use of cash will be classified as operating, investing, or financing activities in accordance with the guidance in ASC 230.
3. If the cash payment or receipt cannot be bifurcated, the entire payment or receipt should be classified as operating, investing, or financing activities on the basis of the activity that is likely to be the predominant source or use of cash. An entity should be consistent in how it classifies cash outflows and inflows. Cash flow classification should be consistent even if doing so creates asymmetry with how the transaction is presented in the balance sheet and income statement. When such asymmetry exists, an entity should include appropriate disclosures that explain such differences.
Connecting the Dots

Since the new guidance is intended to reduce diversity in practice, it could result in significant changes for some entities, particularly with respect to the issues discussed below.

Settlement of Zero-Coupon Bonds

The lack of guidance on the classification of payments to settle zero-coupon bonds in the statement of cash flows has led to diversity in the classification of the cash payment made by a bond issuer at the settlement of a zero-coupon bond. Some entities bifurcate the settlement payment between the principal (the amount initially received by the entity) and accreted interest. In those situations, the portion of the repayment related to principal is classified in financing activities, and the portion related to accreted interest is classified in operating activities. However, other entities do not bifurcate the settlement payment between principal and accreted interest and present the entire repayment in financing activities.

Under the new guidance, entities are required to bifurcate the repayment of zero-coupon bonds into principal and accreted interest, with the principal portion classified in financing activities and the accreted interest portion classified in operating activities. As a result, entities that currently classify the entire repayment of zero-coupon bonds in financing activities will need to identify the portion of such payments that are related to accreted interest and apply the provisions of ASU 2016-15 accordingly.

Further, the consensus that the EITF reached with respect to zero-coupon bonds also applies to other debt instruments with coupon rates that are insignificant in relation to the effective interest rate of the borrowing. An entity will need to use judgment when assessing the significance of the coupon rate since ASU 2016-15 does not provide guidance on how to make such a determination.

Distributions Received From Equity Method Investees

While ASC 230 before the adoption of ASU 2016-15 distinguishes between returns of investment (which should be classified as inflows from investing activities) and returns on investment (which should be classified as inflows from operating activities), it does not prescribe a method for differentiating between the two. With respect to distributions from equity method investees, entities make this determination by applying a cumulative-earnings approach or a nature of the distribution approach. ASU 2016-15 formalizes each of these methods and allows an entity to choose either one as an accounting policy election.

However, ASU 2016-15 requires entities that choose the nature of the distribution approach to report a change in accounting principle if the information required under this approach is unavailable with respect to a particular investee. Therefore, while the ASU will not eliminate diversity in practice, entities that are currently applying the nature of the distribution approach should be mindful of the additional information and disclosure requirements under the ASU in electing a method as their accounting policy.
**Beneficial Interests in Securitization Transactions**

ASC 230 before the adoption of ASU 2016-15 has no specific guidance on how to classify cash receipts associated with beneficial interests in securitization transactions. As a result, entities have classified the subsequent cash receipts from payments on beneficial interests obtained by the transferor in a securitization of the transferor’s trade receivables as either operating activities or investing activities in the statement of cash flows. Although there is diversity in practice, we believe that entities have predominantly presented cash receipts from payments on a transferor’s beneficial interests in securitized trade receivables as a cash inflow from operating activities. Accordingly, the requirement in ASU 2016-15 to present such cash receipts as a cash inflow from investing activities could change practice significantly.

**Separately Identifiable Cash Flows and Application of the Predominance Principle**

ASC 230 before the adoption of ASU 2016-15 acknowledges that certain cash inflows and outflows may have characteristics of more than one cash flow class (e.g., financing, investing, or operating) and states that the “appropriate classification shall depend on the activity that is likely to be the predominant source of cash flows for the item.” Although it provides examples illustrating the application of the predominance principle, entities often have difficulty applying the guidance.

As a result, when cash flows have aspects of more than one cash flow class, ASU 2016-15 requires that entities first determine the classification of those cash receipts and payments by applying the specific guidance in ASC 230 and other applicable ASC topics. In addition, the ASU notes that “[i]n the absence of specific guidance, a reporting entity shall determine each separately identifiable source or each separately identifiable use within the cash receipts and cash payments on the basis of the nature of the underlying cash flows.” The ASU further states that “[i]n situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use . . . , the appropriate classification shall depend on the activity that is likely to be the predominant source or use of cash flows for the item.” However, because the ASU does not define the term “separately identifiable” in this context, we believe that challenges may be presented related to identifying separately identifiable cash receipts and payments as well as applying the term “predominant.”

For more information about ASU 2016-15, see Deloitte’s August 30, 2016, *Heads Up*.

7.3.2 **Restricted Cash**

In November 2016, the FASB issued ASU 2016-18, which amends ASC 230 to add or clarify guidance on the classification and presentation of restricted cash in the statement of cash flows. The ASU was the result of a consensus reached by the EITF and is intended to reduce diversity in practice that has developed related to the cash flow classification of restricted cash. Key requirements of the ASU are as follows:

- An entity should include in its cash and cash-equivalent balances in the statement of cash flows those amounts that are deemed to be restricted cash and restricted cash equivalents. The ASU does not define the terms “restricted cash” and “restricted cash equivalents” but states that an entity should continue to provide appropriate disclosures about its accounting policies pertaining to restricted cash in accordance with other GAAP. The ASU also states that any change in accounting policy will need to be assessed under ASC 250.

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1 See ASC 230-10-45-22 and 45-23.
• A reconciliation between the statement of financial position and the statement of cash flows must be disclosed when the statement of financial position includes more than one line item for cash, cash equivalents, restricted cash, and restricted cash equivalents.

• Changes in restricted cash and restricted cash equivalents that result from transfers between cash, cash equivalents, restricted cash, and restricted cash equivalents should not be presented as cash flow activities in the statement of cash flows.

• An entity with a material balance of amounts generally described as restricted cash and restricted cash equivalents must disclose information about the nature of the restrictions.

For more information about ASU 2016-18, see Deloitte’s November 17, 2016, Heads Up.

7.3.3 Effective Date and Transition

The effective date and transition guidance for both ASU 2016-15 and ASU 2016-18 are consistent. For PBEs, the ASUs became effective for fiscal years beginning after December 15, 2017, including interim periods therein. For all other entities, the ASUs are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted for all entities. Entities must apply the ASUs retrospectively to all periods presented.
Chapter 8 — Income Taxes

8.1 Introduction

The accounting for income taxes under ASC 740 is sometimes very specific and can be complex. The overall objective of accounting for income taxes is to reflect (1) the amount an entity currently owes to tax authorities and (2) a deferred tax asset (DTA) or deferred tax liability (DTL) for the tax effects of the transactions or events that have occurred but that have not yet been reflected in a tax return or vice versa (also referred to as “basis differences” or “temporary differences”). A DTA will be recorded for items that will result in future tax deductions (sometimes referred to as a benefit), and DTLs are recorded for items that will result in the inclusion of future taxable income in an entity’s tax return. This balance sheet approach is used to calculate temporary differences and in effect takes into account the total tax that would be payable (or receivable) if all of an entity’s assets and liabilities were realized at their carrying value at a specific time (the reporting date).

In accordance with ASC 740, the critical event for recognition of a DTA is the event that gives rise to the deductible temporary difference or tax credit or net operating loss (NOL) carryforward. Once that event occurs, those tax benefits should be recognized subject to a realizability assessment. In effect, earning taxable income in future years is treated as a confirmation of realizability and not as a prerequisite to asset recognition. At the same time, management should consider future events to record those DTAs at amounts that are more likely than not to be realized in future tax returns. In the case of DTLs, ASC 740 requires an entity to include in its balance sheet an obligation for the tax consequences of taxable temporary differences even when losses are expected in future years.

The following is a brief summary of deferred tax accounting, in general, under ASC 740:

- DTLs are recognized for future taxable amounts.
- DTAs are recognized for future deductions and operating loss and tax credit carryforwards.
- The marginal tax rate is used to measure DTAs and DTLs.
- A valuation allowance is recognized to reduce DTAs to the amounts that are more likely than not to be realized.
- The amount of the valuation allowance is based on all available positive and negative evidence about the future.
- Deferred tax expense or benefit is computed as the difference between the beginning and ending balance of the net DTA or DTL for the period.
- Upon adoption of ASU 2015-17, entities present DTAs and DTLs as noncurrent in a classified balance sheet.
- The effects of changes in rates or laws are recognized on the date of enactment.
8.2 Industry Issues

The discussions and examples below contain guidance on income tax matters that frequently affect life sciences entities. The guidance cited is not intended to be all-inclusive or comprehensive; rather, it provides targeted considerations related to the application of ASC 740 that are most relevant to the industry.

For more information about the topics summarized below, see Deloitte’s A Roadmap to Accounting for Income Taxes (the “Income Taxes Roadmap”).

8.2.1 Scope Considerations

The scope of ASC 740 is limited to “taxes based on income” when income is determined after revenues and gains are reduced by some amount of expenses and losses allowed by the jurisdiction. Therefore, a tax based solely on revenues would not be within the scope of ASC 740 because the taxable base amount is not reduced by any expenses. A tax based on gross receipts, revenue, or capital should be accounted for under other applicable literature (e.g., ASC 450). In contrast, a tax whose base takes into account both income and expenses is within the scope of ASC 740. Common questions for life sciences entities include whether the medical device excise tax (MDET) and certain R&D credits are within the scope of ASC 740.

Q&A 8-1 Whether the MDET Is Within the Scope of ASC 740

The MDET is a 2.3 percent excise tax on sales of certain medical devices imposed by the Patient Protection and Affordable Care Act of 2010 and Internal Revenue Code (IRC) Section 4191. The tax was scheduled to apply to sales of medical devices on or after January 1, 2018. However, H.R. 195/Public Law 115-120, signed into law on January 22, 2018, extends for two years the moratorium on the MDET imposed by IRC Section 4191. Because of the moratorium, the MDET does not apply to the sale of taxable medical devices by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2019.

**Question**

Is the MDET within the scope of ASC 740?

**Answer**

No. Since the MDET in its current form is based solely on a percentage of total sales (i.e., the applicable rate is applied to total sales, which are not reduced by any expenses), it is not within the scope of ASC 740.

Q&A 8-2 Whether Refundable Tax Credits for Qualifying R&D Are Within the Scope of ASC 740

To promote innovation and spending in their tax jurisdictions, governments frequently provide tax credits to entities with qualifying R&D expenditures. Sometimes these credits ultimately depend on taxable income, in which case the credits are generally recognized as a reduction of income tax regardless of whether they are accounted for under the flow-through method or the deferral method (as described in ASC 740-10-25-45 and 25-46). However, certain tax jurisdictions provide refundable credits for qualifying R&D that do not depend on an entity’s ongoing tax status or tax position (e.g., an entity may receive a refund despite being in a taxable loss position).
**Question**

Are refundable tax credits, as described above, within the scope of ASC 740 and accordingly classified within income tax expense (benefit) in the financial statements?

**Answer**

If realization of the tax credits does not depend on an entity’s generation of future taxable income or an entity’s ongoing tax status or tax position, the credits are not considered to be an element of income tax accounting under ASC 740. Thus, even if the credit claims are filed in connection with a tax return, the refunds are not considered to be part of income taxes and therefore are not within the scope of ASC 740. In such cases, an entity would not record the credits as a reduction of income tax expense; rather, the entity should determine the credits’ classification on the basis of their nature.

When determining the classification of these credits, an entity may consider them to be a form of government grant or assistance. Because there is no direct guidance in U.S. GAAP on this topic, an entity may look to paragraphs 24 and 29 of IAS 20 by analogy. Under paragraph 24 of IAS 20, an entity presents government grants related to assets “either by setting up the grant as deferred income or by deducting the grant in arriving at the carrying amount of the asset.” Further, paragraph 29 of IAS 20 states, “Grants related to income are presented as part of profit or loss, either separately or under a general heading such as ‘Other Income’; alternatively, they are deducted in reporting the related expense.”

In rare circumstances, a tax law may change the way a tax credit is realized. For example, a jurisdiction may have historically required that a credit be realized on the tax return as a reduction in taxes payable but subsequently changes the law so that the credit can be realized without an entity’s first incurring a tax liability (i.e., the credit amount becomes refundable but was not when it arose). In this situation, an entity would generally continue to apply ASC 740 to the credits recognized at the time of the law change. Any new refundable credits earned after the tax law change would be accounted for in accordance with the guidance in this Q&A.

### 8.2.2 Intra-Entity Transfers of IP

Life sciences entities often develop intellectual property (IP) such as drug formulas, trade secrets, know-how, and other proprietary information. This IP may be developed in one jurisdiction but subsequently transferred to a subsidiary in another jurisdiction. Such transfers are often tax-motivated, and both the initial and subsequent accounting for them has historically been complex.

In October 2016, as part of its simplification initiative, the FASB issued ASU 2016-16, which removes the prohibition on recording the current and deferred tax effects of intra-entity transfers of assets other than inventory (the accounting for inventory transfers will remain unchanged). The ASU is intended to reduce the complexity of U.S. GAAP and diversity in practice related to accounting for the tax consequences of certain types of intra-entity asset transfers, including those involving IP.

Under ASC 740-10-25-3(e) before the adoption of ASU 2016-16, a reporting entity is prohibited from immediately recognizing the deferred income tax effects of intra-entity transfers of assets and is required to account for taxes paid on intra-entity profits in accordance with ASC 810-10. ASC 810-10-45-8 before the adoption of ASU 2016-16 states, “If income taxes have been paid on intra-entity profits on assets remaining within the consolidated group, those taxes shall be deferred or the intra-entity profits to be eliminated in consolidation shall be appropriately reduced.” This guidance on intra-entity transfers of assets is applicable to transfers of IP.
Under ASU 2016-16, the selling (transferring) entity is required to recognize any current tax expense or benefit upon transfer of the asset. Similarly, the purchasing (receiving) entity is required to recognize a DTA or DTL, as well as the related deferred tax benefit or expense, upon receipt of the asset. An entity measures the resulting DTA or DTL by (1) computing the difference between the tax basis of the asset in the buyer’s jurisdiction and the asset’s financial reporting carrying value in the consolidated financial statements and (2) multiplying such difference by the enacted tax rate in the buyer’s jurisdiction.

The example below compares the income tax accounting for intra-entity transfers of assets other than inventory under legacy U.S. GAAP with that under ASU 2016-16.

Example 8-1

Consider the following:

Under legacy U.S. GAAP, Subsidiary A recognizes on its tax return a gain of $100 million on the sale of IP to Subsidiary B, which is equal to the proceeds received ($100 million) less the financial reporting carrying value of the IP (zero). However, in accordance with ASC 740-10-25-3(e), A is prohibited from recognizing the current tax expense associated with that $100 million gain. Therefore, upon the sale, A would record the following journal entry for the tax effects:

- Prepaid taxes 30,000,000
- Current taxes payable 30,000,000

Further, B receives a tax basis in the IP of $100 million, which is equal to the amount that it paid to A. This tax basis is greater than the carrying value of the IP in the consolidated financial statements (zero), which would generally result in a DTA. However, in accordance with ASC 740-10-25-3(e), B is prohibited from recognizing the DTA (benefit) associated with its tax-over-book basis difference. Therefore, B would not record any tax entries associated with this transaction.

Under ASU 2016-16, since the exception to recognizing current and deferred taxes on intra-entity transfers of assets other than inventory is removed, A is required to recognize the current tax expense associated with the taxable gain on the sale of the IP by recording the following journal entry:

- Current tax expense 30,000,000
- Current taxes payable 30,000,000

In addition, B is required to recognize the deferred tax effects associated with its purchase of the IP by recording the following journal entry:

- DTA 10,000,000
- Deferred tax benefit 10,000,000
8.2.2.1  **Interim Reporting Considerations**

ASU 2016-16 does not explicitly state whether the tax effects of intra-entity transfers of assets other than inventory should be recognized as discrete items or included in the estimated annual effective tax rate for interim reporting purposes. Paragraph BC13 of the ASU states, in part:

Because of the variety of intra-entity asset transfers, the Board did not want to preclude an entity from making its own assessment about how to treat an intra-entity asset transfer for purposes of the estimate. The Board also agreed with stakeholders who indicated that if the Board had decided that all intra-entity asset transfers should be treated similarly for purposes of the estimate, it would have created an exception to the model in Topic 740. The Board’s view is that it would not be unusual for entities following the guidance to conclude that many intra-entity transfers of assets other than inventory would be treated as discrete items for purposes of the computation. However, the Board understands from stakeholders’ input that because the nature of, frequency of, and ability to estimate these transfers vary among entities, there are circumstances in which an entity could conclude that the transaction should be included in the computation of the estimated annual effective tax rate. The Board understands that an entity will need to apply judgment on the basis of the facts and circumstances to conclude whether the tax consequences of an intra-entity asset transfer other than inventory should be included in the computation of the estimated annual effective tax rate or treated as a discrete item in the interim period in which the transfer occurs.

**Connecting the Dots**

Entities should carefully consider all of the provisions and exceptions in ASC 740-270 to determine whether the tax effects of intra-entity asset transfers are appropriately treated for interim reporting.

8.2.2.2  **Effective Date and Transition**

For PBEs, ASU 2016-16 is effective for annual periods beginning after December 15, 2017, and interim periods therein. For all other entities, the ASU is effective for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. Early adoption is permitted.

Entities should apply the amendments in ASU 2016-16 on a modified retrospective basis, recognizing the effects in retained earnings as of the beginning of the year of adoption.

8.2.3  **Transfer Pricing**

Many life sciences entities are global and operate legal entities in multiple countries. This may simply be owing to the size and scale of the business or may be the result of regulatory requirements. For example, life sciences entities are frequently required to have regulatory approval to manufacture or distribute products in each country in which its products are manufactured or sold. Similarly, contract research organizations (CROs) are often required to perform R&D services on different patient populations in multiple geographical locations. Because of the global nature of many life sciences entities, income tax accounting issues regarding the use of transfer pricing for intra-entity and related-party transactions arise. Generally, transfer pricing is the pricing used for transfers of tangible property, intangible property, services, or financing between affiliated entities in different tax jurisdictions. These transactions include transfers between domestic or international entities, such as (1) U.S. to foreign, (2) foreign to foreign, (3) U.S. to U.S., and (4) U.S. state to state.

The general transfer pricing principle is that the pricing of a related-party transaction should be consistent with the pricing of similar transactions between independent entities under similar circumstances (i.e., an arm’s-length transaction). Transfer pricing tax regulations are intended to prevent entities from using intra-entity charges to evade taxes by inflating or deflating the profits of a particular
jurisdiction in which the larger consolidated group does business. Even if a parent corporation or its subsidiaries are in tax jurisdictions with similar tax rates, an entity may have tax positions that are subject to the recognition and measurement principles in ASC 740-10-25-6 and ASC 740-10-30-7.

An entity's exposure to transfer pricing primarily occurs when the entity includes in its tax return the benefit received from a related-party transaction that was not conducted as though it was at arm's length. An unrecognized tax benefit (UTB) results when one of the related parties reports either lower revenue or higher costs than it can sustain (depending on the type of transaction). While a benefit is generally more likely than not to result from such a transaction (e.g., some amount will be allowed as an interest deduction, royalty expense, or cost of goods sold), the amount of benefit is often uncertain because of the subjectivity of valuing the related-party transaction.

An entity must perform two steps in applying ASC 740 to all uncertain tax positions within its scope: (1) recognition and (2) measurement. The requirements of ASC 740 in the context of transfer pricing arrangements, including related considerations, are outlined below.

### 8.2.3.1 Determining the Unit of Account

Before applying the recognition and measurement criteria, an entity must identify all material uncertain tax positions and determine the appropriate unit of account for assessment. A tax position encompasses “[a]n allocation or a shift of income between jurisdictions” (i.e., a transfer pricing arrangement). Therefore, intra-entity and related-party transactions under transfer pricing arrangements are within the scope of ASC 740.

Further, tax positions related to transfer pricing generally should be evaluated individually, since two entities and two tax jurisdictions are involved in each transaction. Such an evaluation should be performed even when the transaction is supported by a transfer pricing study prepared by one of the entities. Generally, there would be at least two units of account. For example, the price at which one entity will sell goods to another entity will ultimately be the basis the second entity will use to determine its cost of goods sold. See Section 3.30 of Deloitte's *Income Taxes Roadmap* for more information about determining the unit of account.

### 8.2.3.2 Recognition

ASC 740-10-25-6 indicates that the threshold for recognition has been met “when it is more likely than not, based on the technical merits, that the position will be sustained upon examination.” While an entity should apply the recognition threshold and guidance in ASC 740 to tax positions in a transfer pricing arrangement, such tax positions will generally meet the recognition threshold if a transaction has taken place to generate the tax positions and some level of benefit will therefore be sustained. For example, assume that a U.S. parent entity receives a royalty for the use of intangibles by a foreign subsidiary that results in taxable income for the parent and a tax deduction for the foreign subsidiary. The initial tax filing (income in the receiving jurisdiction and expense/deduction in the paying jurisdiction) typically meets the more-likely-than-not recognition threshold on the basis of its technical merits, since a transaction between two parties has occurred. However, because there are two entities and two tax jurisdictions involved, the tax jurisdictions could question whether the income is sufficient, whether the deduction is excessive, or both. Such factors should be considered during the measurement phase as part of the determination of what the tax jurisdictions are more likely than not to accept on the basis of the technical merits.
8.2.3.3 Measurement

After an entity has assessed the recognition criteria in ASC 740 and has concluded that it is more likely than not that the tax position taken will be sustained upon examination, the entity should measure the associated tax benefit. This measurement should take into account all relevant information, including tax treaties and arrangements between tax authorities. As discussed above, each tax position should be assessed individually and a minimum of two tax positions should be assessed for recognition and measurement in each transfer pricing transaction.

For measurement purposes, ASC 740-10-30-7 requires that the tax benefit be based on the amount that is more than 50 percent likely to be realized upon settlement with a tax jurisdiction “that has full knowledge of all relevant information.” Intra-entity or transfer pricing assessments present some unique measurement-related challenges that are based on the existence of tax treaties or other arrangements (or the lack of such arrangements) between two tax jurisdictions.

Measurement of uncertain tax positions is typically based on facts and circumstances. The following are some general considerations (not all-inclusive):

- **Transfer pricing studies** — An entity will often conduct a transfer pricing study with the objective of documenting the appropriate arm’s-length pricing for the transactions. The entity should consider the following when using a transfer pricing study to support the tax positions taken:
  - The qualifications and independence of third-party specialists involved (if any).
  - The type of study performed (e.g., benchmarking analysis, limited or specified method analysis, U.S. documentation report, Organisation for Economic Co-operation and Development (OECD) report).
  - The specific transactions and tax jurisdictions covered in the study.
  - The period covered by the study.
  - The reasonableness of the model(s) and the underlying assumptions used in the study (i.e., comparability of companies or transactions used, risks borne, any adjustments made to input data).
  - Any changes in the current environment, including new tax laws in effect.

- **Historical experience** — An entity should consider previous settlement outcomes of similar tax positions in the same tax jurisdictions. Information about similar tax positions, in the same tax jurisdictions, that the entity has settled in previous years serves as a good indicator of the expected settlement of current positions.

- **Applicability of tax treaties or other arrangements** — An entity should consider whether a tax treaty applies to a particular tax position and, if so, how the treaty would affect the negotiation and settlement with the tax authorities involved.

- **Symmetry of positions** — Even though each tax position should be evaluated individually for appropriate measurement, if there is a high likelihood of settlement through “competent authority” procedures under the tax treaty or other agreement, an entity should generally use the same assumptions about such a settlement to measure both positions (i.e., the measurement assumptions are similar, but the positions are not offset). Under the terms of certain tax treaties entered into by the United States and other foreign jurisdictions, competent authority is a mutual-agreement procedure between countries that is designed to relieve companies of double taxation created by transfer pricing adjustments to previously filed returns.
An entity should carefully consider whether the tax jurisdictions involved strictly follow the arm's-length principle. For example, Brazil has a mandated statutory margin that may or may not equate to what is considered arm's length by another reciprocal taxing jurisdiction. Other jurisdictions that may not strictly follow the arm's-length principle include China and India. In such situations, it may be inappropriate for an entity to assume symmetry of positions when measuring the positions.

### 8.2.3.4 Presentation

UTBs that result from transfer pricing arrangements may give rise to balance sheet presentation issues. For example, an entity with a transfer pricing arrangement may not be able to fully recognize a tax benefit in one jurisdiction but may recognize a tax benefit in the related party's jurisdiction on the basis of the assertion that the entity has competent-authority procedures available and will request that those procedures be applied if one of the tax authorities were to propose an adjustment. As noted above, competent authority is a mutual-agreement procedure between countries that is designed to relieve companies of double taxation created by transfer pricing adjustments to previously filed tax returns. Typically, double-tax cases are resolved under the principles of the transfer pricing guidelines established by the OECD. If an entity elects to take a tax issue to a competent authority for resolution, the manner in which the double-taxation issue is resolved is at the discretion of the respective jurisdictions' competent authorities. To avoid double taxation, one tax authority makes an adjustment (i.e., reduces a cost and increases taxable income) that would require a consistent transfer pricing adjustment (i.e., reducing revenue and decreasing taxable income) in the related party's tax jurisdiction. However, there is no guarantee that an agreement between the jurisdictions will be reached and that double taxation will be avoided.

In some cases, if two governments follow the OECD's transfer pricing guidelines to resolve substantive issues related to transfer pricing transactions between units of the same entity, an asset could be recognized in one jurisdiction because of the application of competent-authority procedures, and a liability could be recognized for UTBs from another tax jurisdiction that arose because of transactions between the entity's affiliates that are not considered at arm's length.

In this case, an entity should present the liability for UTBs and the tax benefit on a gross basis in its balance sheet. In addition, a public entity would include only the gross liability for UTBs in the tabular reconciliation disclosure. However, in the disclosure required by ASC 740-10-50-15A(b), the public entity would include the liability for UTBs and the tax benefit on a net basis in the amount of UTBs that, if recognized, would affect the effective tax rate.

For a more detailed discussion of income tax accounting issues related to transfer pricing, see Chapters 4 and 5 of Deloitte's *Income Taxes Roadmap*.

### 8.2.4 Research and Development

For many life sciences entities, R&D activities represent a significant focus and expenditure. Beyond the above-mentioned scope considerations related to refundable R&D tax credits, these activities may result in various income tax accounting impacts that should be accounted for in accordance with ASC 740. For example, R&D cost-sharing agreements may affect an entity's accounting for the income tax effects of share-based payments. In addition, an entity may acquire R&D assets in a business combination that result in the creation of temporary differences. These issues are summarized below.
8.2.4.1 R&D Cost-Sharing Arrangements

A reporting entity may enter into an arrangement with a related entity (typically a foreign subsidiary) to share the cost of developing certain intangible assets. Under such an arrangement, which is often referred to as a cost-sharing arrangement, one company bears expenses on behalf of another company and is subsequently reimbursed for those costs. The shared costs may include the cost of share-based payments issued to employees of the reporting entity. Regarding the tax impact of the sharing of share-based payment costs, the discussion document for the FASB Statement 123(R) Resource Group’s July 23, 2005, meeting states, in part:

U.S. tax regulations specify the expenses that must be included in a pool of shared costs; such expenses include costs related to stock-based compensation awards granted in tax years beginning after August 26, 2003.

The tax regulations provide two methods for determining the amount and timing of share-based compensation that is to be included in the pool of shared costs: the “exercise method” and the “grant method.” Under the exercise method, the timing and amount of the allocated expense is based on the intrinsic value that the award has on the exercise date. Companies that elect to follow the grant method use grant-date fair values that are determined based on the amount of U.S. GAAP compensation costs that are to be included in a pool of shared costs. Companies must include such costs in U.S. taxable income regardless of whether the options are ultimately exercised by the holder and result in an actual U.S. tax deduction.

Cost-sharing agreements affect the U.S. company’s accounting for the income tax effects of share-based compensation. Companies should consider the impact of cost-sharing arrangements when measuring, on the basis of the tax election they have made or plan to make, the initial DTA and the amount of any future excess tax.

The following example, which is reproduced from the discussion document for the FASB Statement 123(R) Resource Group’s July 23, 2005, meeting, illustrates the accounting for the tax effects of cost-sharing arrangements that involve share-based payments:

Company A, which is located in the United States, enters into a cost-sharing arrangement with its subsidiary, Company B, which is located in Switzerland. Under the arrangement, the two companies share costs associated with the research and development of certain technology. Company B reimburses Company A for 30 percent of the research-and-development costs incurred by Company A. The U.S. tax rate is 40 percent. Cumulative book compensation for a fully vested option is $100 for the year ending on December 31, 2006. The award is exercised during 2007, when the intrinsic value of the option is $150.

The tax accounting-impact is as follows:

**Exercise method:** On December 31, 2006, Company A records $28 as the deferred tax asset related to the option ($100 [book compensation expense] × 70% [percentage not subject to reimbursement] × 40% [tax rate]). When, in 2007, the option is exercised, any net tax benefit that exceeds the deferred tax asset is an excess tax benefit and credited to [additional paid-in capital (APIC)]. The company is entitled to a U.S. deduction [while the discussion document describes this as the deduction, the calculation is actually the tax benefit] (net of the inclusion) of $42 ($150 [intrinsic value when the option is exercised] × 70% [percentage not reimbursed] × 40%). Accordingly, $14 ($42 – $28) would be recorded in APIC.

**Grant method:** The cost-sharing impact is an increase of currently payable U.S. taxes each period; however, in contrast to the exercise method, the cost-sharing method should have no direct impact on the carrying amount of the U.S. deferred tax asset related to share-based compensation. If there was $100 of stock-based compensation during 2006, the impact on the December 31, 2006, current tax provision would be $12 ($100 [book compensation expense] × 30% [percentage reimbursed] × 40%). If the stock-based charge under [ASC 718] is considered a deductible temporary difference, a deferred tax asset also should be recorded in 2006 for the financial statement expense, in the amount of $40 ($100 [book compensation expense] × 40%). The net impact on the 2006 income statement is a tax benefit of $28 ($40 – $12). At settlement, the excess tax deduction of $20 ($50 × 40%) would be recorded in APIC.
ASU 2016-09 became effective for PBEs for annual periods beginning after December 15, 2016, and interim periods therein, and for all other entities, for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. After the adoption of ASU 2016-09, any excess tax benefits under each method described above ($14 under the exercise method example and $20 under the grant method example) would be recorded as a credit to tax expense rather than to APIC.

8.2.4.2 R&D Assets Acquired in a Business Combination

Acquired R&D assets will be separately recognized and measured at their acquisition-date fair values. ASC 350-30-35-17A states that an R&D asset acquired in a business combination must be considered to be an indefinite-lived intangible asset until completion or abandonment of the associated R&D efforts. Once the R&D efforts are complete or abandoned, an entity should apply the guidance in ASC 350 to determine the useful life of the R&D assets and should amortize these assets accordingly in the financial statements. If the project is abandoned, the asset would be written off if it has no alternative use.

In accordance with ASC 740, deferred taxes should be recorded for temporary differences related to acquired R&D assets as of the business combination’s acquisition date. As with all acquired assets and assumed liabilities, an entity must compare the amount recorded for an R&D intangible asset with its tax basis to determine whether a temporary difference exists. If the tax basis of the R&D intangible asset is zero, as it will be in a typical nontaxable business combination, a DTL will be recorded for that basis difference.

8.2.5 Valuation Allowances and Tax-Planning Strategies

A life sciences entity that has recurring losses or other negative evidence must consider all available evidence, both positive and negative, to determine whether a valuation allowance against its DTAs is needed. In assessing positive and negative evidence, an entity must consider the following four possible sources of taxable income discussed in ASC 740-10-30-18:

1. “Future reversals of existing taxable temporary differences.”
2. “Future taxable income exclusive of reversing temporary differences and carryforwards.”
3. “Taxable income in prior carryback year(s) if carryback is permitted under the tax law.”
4. “Tax-planning strategies” (e.g., switching from deducting R&D costs to capitalizing and amortizing the costs for tax purposes).¹

This analysis can be quite complex depending on the entity’s facts and circumstances. Significant judgment is often required, particularly in the evaluation of items (2) and (4) above. It is difficult to assert that the entity will have future taxable income exclusive of reversing taxable temporary differences when it has cumulative losses in recent years. Further, tax-planning strategies must meet certain criteria to be treated as a source of taxable income, and evaluation of those criteria is often not straightforward.

For a detailed discussion of income tax accounting issues related to valuation allowances, see Chapter 4 of Deloitte’s Income Taxes Roadmap. For a discussion of tax-planning strategies in particular, see Sections 4.29 through 4.34 of that Roadmap.

¹ Although this tax-planning strategy has been used by life sciences entities in the past, such entities should keep in mind that the Tax Cuts and Jobs Act (described in Section 8.2.7) includes important changes to the deductibility of research costs. Specifically, that legislation requires companies to spread the cost of research over 5 years rather than allowing them to deduct it all immediately. Moreover, costs related to research conducted offshore will be amortized over 15 years. This particular rule does not become effective until 2021, unlike many other provisions that became effective on January 1, 2018.
8.2.6 Prescription Drug Fees

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, imposed an annual fee, payable to the U.S. Treasury, on the pharmaceutical manufacturing industry for each calendar year beginning on or after January 1, 2011. The amount of the fee to be paid by a given entity is based on the entity’s branded prescription drug (BPD) sales for the preceding year as a percentage of the industry’s BPD sales for the same period. Under current U.S. tax law, the fee is not tax deductible and will therefore result in a permanent difference between an entity’s income for financial reporting purposes and its taxable income. This permanent difference will result in an increase in the entity’s overall effective tax rate.

8.2.7 Tax Reform

On December 22, 2017, President Trump signed into law the tax legislation commonly known as the Tax Cuts and Jobs Act (the “Act”). Under ASC 740, the effects of new legislation are recognized upon enactment, which (for federal legislation) is the date the president signs a bill into law. Accordingly, recognition of the tax effects of the Act was required in the interim and annual periods that included December 22, 2017.

The following provisions of the Act are most likely to be relevant to life sciences entities:

- **Change in corporate tax rate** — The Act reduces the corporate tax rate to 21 percent, effective January 1, 2018, for all corporations. Because ASC 740-10-25-47 requires the effect of a change in tax laws or rates to be recognized as of the date of enactment, all corporations, regardless of their year-end, must have adjusted their DTAs and DTLs as of December 22, 2017. The effect of changes in tax laws or rates on DTAs or DTLs is allocated to continuing operations as a discrete item rather than through the annual effective tax rate.

- **Modification of NOL carryforwards** — The Act modifies aspects of current law regarding NOL carryforwards. Under previous law, NOLs generally had a carryback period of 2 years and a carryforward period of 20 years. The Act eliminates, with certain exceptions, the NOL carryback period and permits an indefinite carryforward period. The amount of the NOL deduction is limited to 80 percent of taxable income, which is computed without regard to the NOL deduction.

- **Deemed repatriation transition tax (IRC Section 965)** — A U.S. shareholder of a specified foreign corporation (SFC) must include in gross income, at the end of the SFC’s last tax year beginning before January 1, 2018, the U.S. shareholder’s pro rata share of certain of the SFC’s undistributed and previously untaxed post-1986 foreign earnings and profits (E&P). The inclusion generally may be reduced by foreign E&P deficits that are properly allocable to the U.S. shareholder. In addition, the mandatory inclusion may be reduced by the pro rata share of deficits of another U.S. shareholder that is a member of the same affiliated group. A foreign corporation’s E&P are taken into account only to the extent that they were accumulated during periods in which the corporation was an SFC (referred to below as a “foreign subsidiary”). The amount of E&P taken into account is the greater of the amounts determined as of November 2, 2017, or December 31, 2017, unreduced by dividends (other than dividends to other SFCs) during the SFC’s last taxable year beginning before January 1, 2018.

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2 SFCs include all controlled foreign corporations and all other foreign corporations (other than passive foreign investment companies) in which at least one domestic corporation is a U.S. shareholder.
The U.S. shareholder's income inclusion is offset by a deduction designed to generally result in an effective U.S. federal income tax rate of either 15.5 percent or 8 percent. The 15.5 percent rate applies to the extent that the SFCs hold cash and certain other assets (the U.S. shareholder's "aggregate foreign cash position"), and the 8 percent rate applies to the extent that the income inclusion exceeds the aggregate foreign cash position.

The Act permits a U.S. shareholder to elect to pay the net tax liability interest free over a period of up to eight years.

- **Global intangible low-taxed income (GILTI)** — Although the Act generally eliminates U.S. federal income tax on dividends from foreign subsidiaries of domestic corporations, it creates a new requirement that certain income (i.e., GILTI) earned by controlled foreign corporations (CFCs) must be included currently in the gross income of the CFCs' U.S. shareholder. GILTI is the excess of the shareholder's "net CFC tested income" over the net deemed tangible income return (the "routine return"), which is defined as the excess of (1) 10 percent of the aggregate of the U.S. shareholder's pro rata share of the qualified business asset investment of each CFC with respect to which it is a U.S. shareholder over (2) the amount of certain interest expense taken into account in the determination of net CFC-tested income.

A deduction is permitted to a domestic corporation in an amount equal to 50 percent of the sum of the GILTI inclusion and the amount treated as a dividend because the corporation has claimed a foreign tax credit as a result of the inclusion of the GILTI amount in income ("IRC Section 78 gross-up"). If the sum of the GILTI inclusion (and related IRC Section 78 gross-up) and the corporation's foreign derived intangible income (FDII) exceeds the corporation's taxable income, the deductions for GILTI and for FDII are reduced by the excess. As a result, the GILTI deduction can be no more than 50 percent of the corporation's taxable income (and will be less if the corporation is also entitled to an FDII deduction). The maximum GILTI deduction is reduced to 37.5 percent for taxable years beginning after December 31, 2025.

- **Deduction for FDII** — The Act allows a domestic corporation a deduction for a portion of its FDII. The amount of the deduction depends, in part, on U.S. taxable income. The percentage of income that can be deducted is reduced in taxable years beginning after December 31, 2025.

- **Base erosion anti-abuse tax (BEAT)** — For tax years beginning after December 31, 2017, a corporation is potentially subject to tax under the BEAT provision if the controlled group of which it is a part has sufficient gross receipts and derives a sufficient level of "base erosion tax benefits." Under the BEAT, a corporation must pay a base erosion minimum tax amount (BEMTA) in addition to its regular tax liability after credits. The BEMTA is generally equal to the excess of (1) a fixed percentage of a corporation's modified taxable income (taxable income determined without regard to any base erosion tax benefit related to any base erosion payment, and without regard to a portion of its NOL deduction) over (2) its regular tax liability (reduced by certain credits). The fixed percentage is generally 5 percent for taxable years beginning in 2018, 10 percent for years beginning after 2018 and before 2026, and 12.5 percent for years after 2025. However, the fixed percentage is 1 percentage point higher for banks and securities dealers (i.e., 6, 11, and 13.5 percent, respectively).

- **Corporate alternative minimum tax (AMT)** — The corporate AMT has been repealed for tax years beginning after December 31, 2017. Taxpayers with AMT credit carryforwards that have not yet been used may claim a refund in future years for those credits even though no income tax liability exists. Companies can continue using AMT credits to offset any regular income tax

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3 Net tax liability under IRC Section 965 is the excess, if any, of the taxpayer's net income tax for the taxable year in which the IRC Section 965 inclusion amount is included over such taxpayer's net income tax for the taxable year, excluding (1) the IRC Section 965 amount and (2) any income or deduction properly attributable to a dividend received by such U.S. shareholder from any deferred foreign income corporation.

4 Note that taxpayers should consider whether other limitations (e.g., IRC Section 383) apply to their ability to claim a refund of AMT.
liability in years 2018 through 2020, with 50 percent of remaining AMT credits refunded in each of the 2018, 2019, and 2020 tax years and all remaining credits refunded in tax year 2021.

- **Modified or repealed deductions** — Various provisions of previous tax law related to deductions have been modified or repealed, including the following:
  - *Capital expensing* — Previous law included provisions for the deduction of qualifying property purchases and the depreciation of capital assets. The Act permits 100 percent immediate expensing for qualified property through 2022, which is phased down each subsequent year through 2026 (80 percent in 2023, 60 percent in 2024, 40 percent in 2025, 20 percent in 2026).
  - *Business interest payments* — Previous law generally permitted deductions for business interest payments, with some limits in IRC Section 163(j). The Act limits deductions to business interest income plus 30 percent of adjusted taxable income.
  - *Manufacturing deduction* — Previous law under IRC Section 199 provided for a 9 percent deduction equal to the lesser of qualified production activity income or taxable income. The Act repeals this deduction.
  - *Orphan drug credit* — The Act halves the credit for research on rare diseases, known as the orphan drug credit.
  - *Research and experimentation (R&E) expenses* — Previous law permitted immediate expensing of R&E costs. The Act requires R&E costs to be amortized over 5 years for R&E activities performed in the United States (or 15 years for R&E activities performed outside the United States).

For responses to frequently asked questions about how an entity should account for the tax effects of the Act in accordance with ASC 740, see Deloitte’s January 3, 2018, Financial Reporting Alert (last updated August 30, 2018). For a discussion of other matters related to the income tax accounting consequences of the Act’s provisions, see Deloitte’s January 12, 2018, Financial Reporting Alert.

### 8.3 SEC Comment Letter Themes Related to Income Taxes

The SEC staff’s comments about income taxes continue to focus on (1) valuation allowances, (2) disclosures related to the income tax rate, (3) tax effects of significant or unusual transactions that occurred during the period, and (4) noncompliance with disclosure requirements (e.g., omission of required disclosures).

Further, the SEC staff continues to ask registrants to provide early-warning disclosures to help financial statement users understand key estimates and assumptions in recording these items and how changes to those estimates and assumptions could potentially affect the financial statements in the future. The SEC staff also continues to issue comments on non-GAAP measures with a particular focus on the income tax impact of the adjustments made to the GAAP measures. For additional information about non-GAAP measures, see Deloitte’s A Roadmap to Non-GAAP Financial Measures.

Historically, the SEC staff has stated that boilerplate language should be avoided with respect to income tax disclosures within MD&A and that approaches more conducive to effective disclosure would include:

- Using the income tax rate reconciliation as a starting point and describing the details of the material items.
- Discussing significant foreign jurisdictions, including statutory rates, effective rates, and the current and future impact of reconciling items.
- Providing meaningful disclosures about known trends and uncertainties, including expectations regarding the countries where registrants operate.
For more information about SEC comment letter themes that pertain to the life sciences industry, see Deloitte’s *A Roadmap to SEC Comment Letter Considerations, Including Industry Insights*.

### 8.4 New Accounting Standard — Reclassification of Certain Tax Effects From Accumulated Other Comprehensive Income (ASU 2018-02)

#### 8.4.1 Background

Stakeholders raised a narrow-scope financial reporting issue that arose as a consequence of the Act. Some constituents expressed concerns about the requirement in ASC 740 that the effect of a change in tax laws or rates on DTAs and DTLs be included in income from continuing operations in the reporting period that contains the enactment date of the change. That guidance applies even in situations in which the tax effects were initially recognized directly in other comprehensive income (OCI) at the previous rate, resulting in “stranded” amounts in accumulated other comprehensive income (AOCI) related to the income tax rate differential.

In February 2018, the FASB issued *ASU 2018-02* to address concerns related to the application of ASC 740. The amendments in the ASU allow a reclassification from AOCI to retained earnings for stranded tax effects resulting from the Act. The ASU affects any entity that (1) is required to apply the guidance in ASC 220 and (2) has items of OCI for which the related tax effects are presented in OCI as required under U.S. GAAP.

#### 8.4.2 Key Provisions

Upon adopting ASU 2018-02, an entity is required to disclose:

- Its accounting policy related to releasing income tax effects from AOCI (e.g., the portfolio approach or the security-by-security approach).
- Whether it has elected to reclassify, to retained earnings in the statement of stockholders’ equity, the stranded tax effects in AOCI related to the Act.
- If it has elected to reclassify to retained earnings the stranded tax effects in AOCI related to the Act, what the reclassification encompasses (whether it includes only the change in the federal corporate tax rate or whether it also includes other changes resulting from the Act that affect AOCI). Other effects might include, for example, the income tax effects of accounting for foreign subsidiaries when a DTL had previously been recorded for an excess of the amount for financial reporting over the tax basis in the investments.

#### 8.4.3 Effective Date and Transition

The guidance in the ASU is effective for fiscal years beginning after December 15, 2018, including interim periods therein, and early adoption is permitted. An entity will apply this guidance to each period in which the effect of the Act (or portion thereof) is recorded and may apply it either (1) retrospectively as of the date of enactment or (2) as of the beginning of the period of adoption. The Board decided to permit early adoption for PBEs for which financial statements have not yet been issued and for all other entities for which financial statements have not yet been made available for issuance.


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5 For more information about the portfolio approach and the security-by-security approach, see Section 7.18 of Deloitte’s *Income Taxes Roadmap*.
Chapter 8 — Income Taxes

8.5 On the Horizon — Proposed ASU on Disclosure Requirements for Income Taxes

8.5.1 Background

In July 2016, the FASB issued a proposed ASU on the disclosure framework for income taxes that would modify or eliminate certain disclosure requirements related to income taxes as well as establish new requirements. The proposal is part of the FASB’s disclosure framework project, which, as noted on the Board’s related Project Update page, is intended to “improve the effectiveness of disclosures in notes to financial statements by facilitating clear communication of the information required by generally accepted accounting principles (GAAP) that is most important to users of each entity’s financial statements.”

For additional information about the proposed ASU, see Deloitte's July 29, 2016, Heads Up.

At its meeting on November 14, 2018, the FASB discussed comments received on the proposed ASU and reached several tentative decisions related to many of the proposed ASU's disclosure requirements. The Board also discussed whether additional disclosures should be considered as a result of the Act. For more information about the Board’s tentative decisions, see Deloitte's November 20, 2018, journal entry.

8.5.2 Key Provisions

8.5.2.1 Scope

Although many of the proposed amendments would apply to all entities that are subject to income taxes, some of them would apply only to PBEs.

8.5.2.2 Tax Cuts and Jobs Act

The Board tentatively concluded that the existing guidance in ASC 740 adequately addresses the Act’s provisions; however, the Board requested that the FASB staff perform further research related to the Act’s deemed repatriation transition tax to determine whether additional disclosure may be warranted.

8.5.2.3 Indefinitely Reinvested Foreign Earnings

The proposed ASU would have required all entities to explain any change to an indefinite reinvestment assertion made during the year, including the circumstances that caused such change in assertion. All entities would have also been required to disclose the amount of earnings for which there was a change in assertion made during the year. In addition, all entities would have been required to disclose the aggregate of cash, cash equivalents, and marketable securities held by their foreign subsidiaries.

As noted above, the Act introduced the concept of the transition tax, which has significantly reduced the amount of untaxed foreign earnings held by entities with foreign operations. As a result, during its November 14, 2018, meeting, the Board voted to remove the proposed disclosure requirements related to indefinitely reinvested foreign earnings. For reasons similar to those noted above, the Board also voted to remove the existing requirement in ASC 740-30-50-2(b) to disclose the “cumulative amount of each type of temporary difference” when a “deferred tax liability is not recognized because of the exceptions to comprehensive recognition of deferred taxes related to subsidiaries and corporate joint ventures.” This disclosure requirement was not included in the proposed ASU.
8.5.2.4 Unrecognized Tax Benefits

The proposed ASU would have modified the disclosure requirements for a PBE related to UTBs by adding a requirement for entities to disclose, in the tabular reconciliation of the total amount of UTBs required by ASC 740-10-50-15A(a), settlements disaggregated by those that have been (or will be) settled in cash and those that have been (or will be) settled by using existing DTAs (e.g., settlement by using existing NOL or tax credit carryforwards).

A PBE would have also been required to provide a breakdown (i.e., a mapping) of the amount of total UTBs shown in the tabular reconciliation by the respective balance-sheet lines on which such UTBs are recorded. If a UTB is not included in a balance-sheet line, such amount would be disclosed separately. In addition, a PBE would have been required to disclose the total amount of UTBs that are offset against existing DTAs for NOL and tax credit carryforwards.

Under the guidance currently in ASC 740-10-50-15(d), all entities must disclose details of tax positions for which it is reasonably possible that the total amount of UTBs will significantly increase or decrease in the next 12 months. The proposed ASU would eliminate this disclosure requirement.

ASC 740-10-55-217 (as amended) would provide an example of the applicability of these disclosure requirements.

At its November 14, 2018, meeting, the Board voted to remove the proposed disclosure requirement for entities to disclose, in the tabular reconciliation of the total amount of UTBs, settlements disaggregated by those that have been (or will be) settled in cash as well as those that have been (or will be) settled by using existing DTAs. In contrast, the Board voted to retain the proposed requirement for PBEs to disclose the line items in the statement of financial position in which UTBs are presented and the related amounts of such UTBs. However, the Board voted to remove the proposed requirement to separately disclose a UTB that is not included in a balance-sheet line item because it was unclear to which UTBs this proposed requirement would now relate. Finally, the Board affirmed the proposed removal of the disclosure requirement in ASC 740-10-50-15(d).

8.5.2.5 Operating Loss and Tax Credit Carryforwards

Currently, entities are required to disclose the amount and expiration dates of operating losses and tax credit carryforwards for tax purposes. Historically, there has been diversity in practice related to this disclosure requirement. The proposed ASU would have reduced this diversity by requiring a PBE to disclose the total amount of:

- Federal, state, and foreign gross NOL and tax credit carryforwards (i.e., not tax effected) by period of expiration for each of the first five years after the reporting date and a total for any remaining years.
- Federal, state, and foreign DTAs related to NOL and tax credit carryforwards (i.e., tax effected) before any valuation allowance.

As discussed previously, a PBE would also be required to disclose the total amount of UTBs that are offset against existing DTAs for NOL and tax credit carryforwards.

In addition, the proposed ASU would modify the disclosure requirement related to NOL and tax credit carryforwards for entities other than PBEs. An entity other than a PBE would be required to disclose the total gross amounts of federal, state, and foreign NOL and tax credit carryforwards (i.e., not tax effected) along with their expiration dates.
ASC 740-10-55-218 through 55-222 (as amended) would provide an example of the applicability of these disclosure requirements.

At its November 14, 2018, meeting, the Board determined that disclosure of the not-tax-effected amounts of federal, state, and foreign gross NOL and tax credit carryforwards did not provide decision-useful information and voted to remove the proposed requirement for PBEs. However, the Board concluded that disclosure of the tax-effected amounts of federal, state, and foreign deferred tax assets related to NOL and tax credit carryforwards was useful and therefore voted to retain the proposed disclosure requirement for PBEs with a modification that they also disclose the valuation allowance associated with such amounts. Regarding entities other than PBEs, the Board voted to retain the proposed disclosure requirement in ASC 740-10-50-8A for these entities to disclose total amounts of federal, state, and foreign NOL and tax credit carryforwards on a not-tax-effected basis.

### 8.5.2.6 Rate Reconciliation

ASC 740-10-50-12 currently requires a PBE to disclose a reconciliation of the reported amount of income tax expense (or benefit) from continuing operations to the amount of income tax expense (or benefit) that would result from multiplying the pretax income (or loss) from continuing operations by the domestic federal statutory tax rate.

The proposed ASU would amend the requirement for a PBE to disclose the income tax rate reconciliation in a manner consistent with SEC Regulation S-X, Rule 4-08(h). As amended, ASC 740-10-50-12 would continue to require a PBE to disclose a reconciliation of the reported amount of income tax expense (or benefit) from continuing operations to the amount of income tax expense (or benefit) that would result from multiplying the pretax income (or loss) from continuing operations by the domestic federal statutory tax rate. However, the amendment would modify the requirement to disaggregate and separately present components in the rate reconciliation that are greater than or equal to 5 percent of the tax at the statutory rate in a manner consistent with the requirement of Rule 4-08(h).

The Board, at its November 14, 2018, meeting, voted to affirm the proposed amendment to ASC 740-10-50-12.

### 8.5.2.7 Government Assistance

As a result of deliberations on its November 2015 proposed ASU on government assistance, the FASB decided to require an entity to disclose certain information related to assistance received from a governmental unit that reduces the entity’s income taxes. Accordingly, the July 2016 proposed ASU on income tax disclosure requirements would require all entities that receive income tax–related government assistance to disclose a “description of a legally enforceable agreement with a government, including the duration of the agreement and the commitments made with the government under that agreement and the amount of benefit that reduces, or may reduce, its income tax burden.” This disclosure requirement would apply only when the government determined whether, under such agreement, the entity would receive assistance and, if so, how much it would receive even if it met the applicable eligibility requirements.

In the absence of a specific agreement between the entity and the government, the entity would not be required to disclose this information if the entity obtained the government assistance because it met eligibility requirements that apply to all taxpayers.

The Board, at its November 14, 2018, meeting, voted to affirm the proposed disclosure requirements for government assistance. For more information about disclosures entities must make about government assistance they receive, see Section 13.1.
8.5.2.8 Other Income Tax Disclosure Requirements

The July 2016 proposed ASU would have required all entities to disclose the following:

- The amount of pretax income (or loss) from continuing operations disaggregated by foreign and domestic amounts.
- The amount of income tax expense (or benefit) from continuing operations disaggregated by foreign and domestic amounts.
- The amount of income taxes paid disaggregated by foreign and domestic amounts. A further disaggregation would be required for any country that is significant to the total amount of income taxes paid.
- An enacted tax law change if it is probable that such change would have an effect on the entity in the future.

In addition, the proposed ASU would require PBEs to explain any valuation allowance recognized or released during the year along with the corresponding amount.

At its November 14, 2018, meeting, the Board ultimately voted to retain the disaggregated presentation of income (or loss) from continuing operations and the amount of income tax expense (or benefit) but voted to remove the requirement related to income taxes paid. The Board also voted to clarify that the amount of pretax income (or loss) from continuing operations presented in the disaggregation should be on a "preconsolidated" basis. Further, the Board voted to affirm the proposed disclosure requirement for PBEs to explain any valuation allowance recognized or released during the year along with the corresponding amount.

Connecting the Dots

The proposed ASU on income tax disclosure requirements is also aligned with the FASB’s September 2015 proposed ASU on assessing the materiality of disclosures, which would allow an entity to consider materiality when assessing income tax disclosure requirements. For additional information about the September 2015 proposed ASU, see Deloitte’s September 28, 2015, Heads Up.

8.5.3 Interim Disclosure Requirements

The July 2016 proposed ASU did not contain changes to interim disclosure requirements. However, the Board, at its November 14, 2018, meeting, voted to add an interim disclosure requirement to disclose income taxes paid for all interim periods presented.

8.5.4 Effective Date and Transition

The proposed ASU would be applied prospectively. The FASB will determine an effective date for the final guidance after it has considered feedback from stakeholders.

8.5.5 Recent Board Decisions

The FASB continued redeliberations of the proposed ASU at its January 23, 2019, meeting. Specifically, as stated in its tentative Board decisions:

The Board discussed external review comments on a draft of a revised proposed Update, including whether tax expense and taxes paid on foreign earnings that are imposed by the country of domicile of the entity should be classified as a foreign or domestic amount.
The Board decided not to require that an entity disclose the amount of the transition tax liability resulting from the Tax Cuts and Jobs Act and the line item in the statement of financial position in which the liability is presented.

The Board also decided not to require that an entity disclose a description of a legally enforceable agreement with a government, including the duration of the agreement, the commitments made with the government under that agreement, and the amount of benefit that reduces or may reduce its income tax burden.

The Board directed the staff to perform outreach on the operability and benefits of classifying tax expense and taxes paid on foreign earnings that are imposed by the country of domicile of the entity as a foreign or domestic amount.
Chapter 9 — Compensation

9.1 Accounting for Share-Based Payment Arrangements With Nonemployees (ASU 2018-07)

In June 2018, the FASB issued ASU 2018-07, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees is aligned with the requirements for share-based payments granted to employees.

Currently, share-based payment arrangements with employees are accounted for under ASC 718, while nonemployee share-based payments issued for goods and services are accounted for under ASC 505-50. ASC 505-50, before the ASU's amendments, differs significantly from ASC 718. Differences include (but are not limited to) the guidance on (1) the determination of the measurement date (which generally is the date on which the measurement of equity-classified share-based payments becomes fixed), (2) the accounting for performance conditions, (3) the ability of a nonpublic entity to use certain practical expedients for measurement, and (4) the accounting (including measurement and classification) for share-based payments after vesting.

9.1.1 Key Provisions

9.1.1.1 Scope

ASU 2018-07 supersedes ASC 505-50 and expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. As a result, most of the guidance in ASC 718, including most of its requirements related to classification and measurement, would apply to nonemployee share-based payment arrangements.

9.1.1.2 Measurement Date

One of the more significant changes under ASU 2018-07 is related to the determination of the measurement date, which is generally the date on which the measurement of equity-classified share-based payments becomes fixed. ASU 2018-07 eliminates the guidance in ASC 505-50 on determining the measurement date for nonemployee share-based payment arrangements. Rather, for equity-classified awards, the measurement date would generally be the grant date.
9.1.1.3 Vesting Conditions

Under ASC 718, service and performance conditions are vesting conditions, while market conditions are incorporated into the fair-value-based measurement of share-based payments. ASU 2018-07 extends that guidance to nonemployee awards and modifies the definitions of service and performance conditions to incorporate characteristics of nonemployee awards. Accordingly, the ASU expands the definition of a service condition to include “a nonemployee delivering goods or rendering services to the grantor over a vesting period” and the definition of a performance condition to include the “performance of the grantee if such performance is in accordance with the terms of the award and solely relates to the grantor’s own operations (or activities).”

The treatment of nonemployee share-based payment performance conditions under ASU 2018-07 is significantly different from that under existing guidance. In recognizing the cost of nonemployee awards, an entity generally is precluded by ASC 505-50 from considering whether it is probable that the performance conditions will be met. Rather, if the quantity and terms of nonemployee awards depend on counterparty performance conditions, the entity measures any cost recognized on the basis of the “then-current lowest aggregate fair value” of the awards as of each reporting period until the performance conditions are “known” (i.e., achieved). This can often result in a scenario in which the lowest aggregate fair value is zero and no cost is recognized until the performance conditions are achieved, even if the performance conditions are expected to be met. Under ASU 2018-07, the guidance on nonemployee awards with performance conditions is aligned with that in ASC 718. Accordingly, an entity is required to recognize any cost on the basis of the probable outcome of performance conditions.

9.1.1.4 Forfeitures

As in the case of employee awards, ASU 2018-07 permits an entity to make an entity-wide policy election for all nonemployee awards to either (1) estimate forfeitures or (2) recognize forfeitures when they occur. The policy election is independent of the entity’s policy election for employee awards. If the entity elects to estimate forfeitures, it should recognize the cost of nonemployee awards on the basis of its estimate of awards for which the goods are expected to be delivered or the service is expected to be rendered, and the entity should revise its estimate as appropriate.

9.1.1.5 Fair-Value-Based Measurement

Under ASC 505-50, nonemployee share-based payment awards are measured at the fair value of either the consideration received (i.e., fair value of the goods or services received) or the equity instruments issued, whichever is more reliably measurable. In practice, such awards generally are measured on the basis of the fair value of the equity instruments issued. Under ASU 2018-07, nonemployee awards are always measured on the basis of the fair value of the equity instruments issued, in a manner consistent with the measurement for employee awards. However, in calculating the fair-value-based measurement of nonemployee stock options and similar instruments, an entity can elect on an award-by-award basis to use the contractual term as the expected term.
9.1.1.6 Practical Expedients for Nonpublic Entities

ASU 2018-07 permits nonpublic entities to use the same practical expedients as those provided for measuring employee awards. Specifically, ASU 2018-07 allows nonpublic entities to use the following practical expedients:

- **Calculated value** — A nonpublic entity is required to use "calculated value" to measure its stock options and similar instruments granted to nonemployees if it is unable to reasonably estimate the fair value of such awards because it is not practicable for it to estimate the expected volatility of its stock price.

- **Intrinsic value** — A nonpublic entity may measure all liability-classified share-based payment awards granted to nonemployees at intrinsic value instead of fair value. If an entity has already elected to apply the practical expedient to employee awards, that election would also apply to nonemployee awards (i.e., this practical expedient must be consistently applied to both employee and nonemployee awards).

- **Expected term** — A nonpublic entity that does not elect to use the contractual term as the expected term of an award may, as a practical expedient, estimate the expected term for nonpublic stock options and similar awards granted to nonemployees that meet the conditions in ASC 718-10-30-20B. The practical expedient is an entity-wide accounting policy election that must be consistently applied to both employee and nonemployee awards. Under the practical expedient, the expected term is generally estimated as the midpoint between the nonemployee vesting period and the contractual term of the award.¹

9.1.1.7 Classification

The guidance in ASC 718 on the classification of employee share-based payment awards also applies to nonemployee awards under ASC 505-50 before they vest. However, under ASC 505-50, nonemployee awards become subject to other guidance in U.S. GAAP that generally applies to financial instruments (e.g., ASC 815) once performance is complete (i.e., the awards are vested). By contrast, employee awards remain within the scope of ASC 718 (even after they vest) unless they are modified after the holder ceases to be an employee (except under an equity restructuring that meets certain criteria). Since ASU 2018-07 aligns the classification treatment of employee and nonemployee awards, nonemployee awards will generally remain within the scope of ASC 718 unless they are modified after the awards vest and the nonemployee is no longer providing goods and services (except under an equity restructuring that meets certain criteria).

9.1.2 Transition and Related Disclosures

ASU 2018-07 generally requires an entity to use a modified retrospective transition approach, with a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year, for all (1) liability-classified nonemployee awards that have not been settled as of the adoption date and (2) equity-classified nonemployee awards for which a measurement date has not been established. In the application of a modified retrospective approach:

- ASU 2018-07's transition provisions do not apply to equity-classified awards for which a measurement date was previously established under ASC 505-50 because of the existence of a performance commitment or because performance was complete.

- ASU 2018-07 requires equity-classified awards (for which a measurement date has not been previously established) to be remeasured on the basis of their adoption-date fair-value-based measure.

¹ An exception to using the midpoint is an award that has an implicit vesting period and a performance condition that is not probable of being met. In this circumstance, the expected term is the contractual term.
• An entity applies the guidance on modifications of an award from liability to equity classification (i.e., the unsettled liability award as measured on the adoption date would be reclassified to equity) to determine the cumulative-effect adjustment to equity for unsettled awards that are currently classified as a liability but will be classified as equity under ASU 2018-07.

• An entity should not adjust the basis of assets that include nonemployee share-based payment costs if the assets are completed (e.g., finished goods inventory or fixed assets for which amortization has commenced).

However, if a nonpublic entity changes its measurement of nonemployee awards to calculated value instead of a fair-value-based measure, the ASU requires the entity to use a prospective approach.

In the first interim and fiscal year of adoption, an entity is required to disclose the following:

• The nature of and reason for the change in accounting principle.

• The cumulative effect of the change on retained earnings in the statement of financial position as of the beginning of the period of adoption.

9.1.3 Effective Date

For PBEs, the amendments in ASU 2018-07 are effective for fiscal years beginning after December 15, 2018, including interim periods therein. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted if financial statements have not yet been issued (for PBEs) or have not yet been made available for issuance (for all other entities), but no earlier than an entity's adoption date of ASC 606.

For more information about ASU 2018-07, see Appendix E of Deloitte's A Roadmap to Accounting for Share-Based Payment Awards.

9.2 Emerging Growth Companies — Common-Stock Repurchase Transactions

Various stock transactions with employees of a nonpublic emerging growth company (the “nonpublic entity”) involve significant judgment and complexities that may have a material impact on the nonpublic entity's financial statements. In addition, such transactions often have certain tax implications for both the nonpublic entity and its employees. These stock transactions can be between the nonpublic entity and its employees, a preexisting investor and the nonpublic entity's employees, or a new investor and the nonpublic entity's employees.

9.2.1 Accounting Considerations

9.2.1.1 Transactions Directly Between a Nonpublic Entity and Its Employees

When a nonpublic entity repurchases common shares from its employees at an amount greater than the estimated fair value of the shares at the time of the transaction, the excess of the purchase price over the fair value of the common shares generally represents employee compensation.

2 The FASB retained the current definitions in ASC 718 of a public entity and a nonpublic entity for use in the determination of whether a nonpublic entity practical expedient can be elected. However, an entity will determine the ASU's effective date on the basis of whether it meets the ASC master glossary's definition of a PBE.
ASC 718-20-35-7 states the following:

The amount of cash or other assets transferred (or liabilities incurred) to repurchase an equity award shall be charged to equity, to the extent that the amount paid does not exceed the fair value of the equity instruments repurchased at the repurchase date. Any excess of the repurchase price over the fair value of the instruments repurchased shall be recognized as additional compensation cost. An entity that repurchases an award for which the requisite service has not been rendered has, in effect, modified the requisite service period to the period for which service already has been rendered, and thus the amount of compensation cost measured at the grant date but not yet recognized shall be recognized at the repurchase date. [Emphasis added]

For example, a nonpublic entity may repurchase shares from its existing employees in connection with a convertible preferred stock financing, whereby the entity may set aside a specified amount of the financing to repurchase common stock from its existing employees and thereby provide liquidity to its employees. It is not unusual for an entity to repurchase common shares by using the price established for the preferred stock in the most recent round of financing. Accordingly, a nonpublic entity would need to evaluate whether the price of the preferred stock is equal to the value of the common stock. Typically, the value of preferred shares will exceed the value of common shares (assuming one-to-one conversion) because of preferential rights normally associated with preferred shares. As a result, the excess amount would be reflected in the nonpublic entity’s financial statements as compensation cost in accordance with ASC 718-20-35-7.

9.2.1.2 Transactions Directly Between a Preexisting Investor and the Nonpublic Entity’s Employees as Part of a Financing Transaction

Occasionally, investors intending to increase their stake in an emerging nonpublic entity may undertake transactions with other shareholders in connection with a recent financing round. These transactions may include investors’ purchase of common shares directly from the founders of the nonpublic entity or other individuals who are also considered employees of the nonpublic entity. Because the transactions are between employees of the nonpublic entity and existing shareholders and are related to the transfer of outstanding shares, the nonpublic entity may not be directly involved in them (although it may become indirectly involved by facilitating the exchange or not exercising a right of first refusal).

If there is sufficient evidence that a transaction is an arm’s-length fair value transaction, it may be necessary to treat the transaction as a data point in the estimation of the fair-value-based measurement of share-based payment awards. If a transaction involves founders or a few select key employees, however, it may be difficult to demonstrate that the transaction is not compensatory. If the price paid for the shares exceeds their fair value at the time of the transaction, it is likely that the nonpublic entity will be required to recognize compensation cost for the excess regardless of whether the entity is directly involved in the transaction. It is important for a nonpublic entity to recognize that transactions such as these may be subject to the guidance in ASC 718 because the investors are considered to be holders of an economic interest in the entity.

ASC 718-10-15-4 states the following:

Share-based payments awarded to an employee of the reporting entity by a related party or other holder of an economic interest[3] in the entity as compensation for services provided to the entity are share-based payment transactions to be accounted for under this Topic unless the transfer is clearly for a purpose other than compensation for services to the reporting entity. The substance of such a transaction is that the economic interest holder makes a capital contribution to the reporting entity, and that entity makes a share-based payment to its employee in exchange for services rendered. An example of a situation in which such a transfer is not compensation is a transfer to settle an obligation of the economic interest holder to the employee that is unrelated to employment by the entity. [Emphasis added]

3 ASC 718-10-20 defines an economic interest in an entity as “[a]ny type or form of pecuniary interest or arrangement that an entity could issue or be a party to, including equity securities; financial instruments with characteristics of equity, liabilities, or both; long-term debt and other debt-financing arrangements; leases; and contractual arrangements such as management contracts, service contracts, or intellectual property licenses.”
Although the presumption in such transactions is that any consideration in excess of the fair value of the shares is compensation paid to employees, nonpublic entities should consider whether the amount paid is related to an existing relationship or to an obligation that is unrelated to the employees' services to the entity in assessing whether the payment is “clearly for a purpose other than compensation for services to the reporting entity.”

9.2.1.3  Transactions Directly Between a New Investor and the Nonpublic Entity's Employees as Part of a Financing Transaction

Transactions between a new investor and a nonpublic entity's employees need to be given consideration similar to that given to transactions between a preexisting investor and a nonpublic entity's employees. If, in connection with a financing transaction, a new investor repurchases common shares in the nonpublic entity from employees of the nonpublic entity, there may be compensation expense that should be recognized. Although the new investor did not hold an economic interest before entering into the transaction with the nonpublic entity, the new investor is not dissimilar to a party that already holds economic interest in the nonpublic entity and may have similar motivations to compensate employees. As noted in ASC 718-10-15-4, a share-based payment arrangement between the holder of an economic interest in a nonpublic entity and an employee of the nonpublic entity should be accounted for under ASC 718 unless the arrangement is clearly for a purpose other than compensation for services.

9.2.2  Valuation Considerations

While the examples above describe situations in which it is likely that the nonpublic entity would recognize additional compensation cost, we are aware of fact patterns in which a secondary market transaction between an investor and a nonpublic entity's employees represents an orderly arm's-length transaction conducted at fair value. In these fact patterns, the nonpublic entity can adequately support a conclusion that the transaction was conducted at fair value and therefore did not result in additional compensation cost. Often, the stock repurchase is a secondary market transaction, the nonpublic entity does not enter into a separate financing transaction concurrently, and the investor has not acquired a significant ownership interest in the nonpublic entity. If the nonpublic entity can support a conclusion that the stock repurchase transaction was conducted at fair value and was not compensatory, we would expect the entity to incorporate the transaction into its common-stock valuation, which a third-party valuation firm typically performs to ensure compliance with IRC Section 409A and determine the fair-value-based measure of the nonpublic entity's share-based payment arrangements. For this type of transaction, we would expect the nonpublic entity to consider both compensatory and noncompensatory indicators when evaluating the substance of the transaction.

Upon determining that a secondary market transaction is noncompensatory, a nonpublic entity should consider the guidance in paragraph 8.07 of the AICPA Accounting & Valuation Guide Valuation of Privately-Held-Company Equity Securities Issued as Compensation when assessing whether it should factor the secondary market transaction into its IRC Section 409A valuation for determining the fair value of its common stock. See Deloitte's June 6, 2018, Financial Reporting Alert for a summary of this guidance as well as a flowchart detailing the steps outlined in the guidance.

9.2.3  Tax Considerations

For tax purposes, stock repurchases are generally treated either as capital (e.g., capital gain) or as dividend-equivalent redemptions (e.g., ordinary dividend income to the extent of earnings and profits). Repurchases from current or former service providers (i.e., current or former employees or independent contractors) give rise to an additional question about whether any of the proceeds should be treated as compensation for tax purposes.
In the assessment of whether a portion of the payment is compensation, a critical tax issue is what value is appropriate for the nonpublic entity to use when determining the effect of the capital redemption. That is, the nonpublic entity must determine whether some portion of the consideration for the repurchase represents something other than fair value for the common stock (i.e., compensation cost). When a repurchase exceeds the fair value of the common stock, there is risk that some of the purchase consideration is compensation for tax purposes. The determination of whether such excess is compensatory depends on the facts and circumstances, and **there can be disparate treatment for book and tax purposes with respect to compensation transactions** along with ambiguity in the existing tax code. Relevant factors include whether the repurchase is (1) performed by the nonpublic entity or an existing investor or (2) part of arm’s-length negotiations with a new investor, who may not have the same information as the nonpublic entity about what is considered to be the fair market value of the stock. If the purchaser is not the nonpublic entity, it is relevant whether the shares will be held by the buyer, or whether they can be converted into a different class of stock or put back to the nonpublic entity. Another factor is whether an offer to sell at a higher price is limited to service providers or is available to shareholders more generally.

While any tax liability resulting from additional compensation is the obligation of the individual, the nonpublic entity has an obligation to (1) withhold income and payroll taxes from payments to employees and (2) remit the employer share of payroll tax. If the nonpublic entity does not withhold payroll taxes from an employee in a transaction when the excess purchase price is compensatory, the nonpublic entity becomes responsible for the tax and should evaluate whether it should accrue a liability in accordance with ASC 450, which addresses the proper accounting treatment of non-income-tax contingencies such as sales and use taxes, property taxes, and payroll taxes.

An estimated loss contingency, such as a payroll tax liability, is accrued (i.e., expensed) if (1) it is probable that the liability has been incurred as of the date of the financial statements and (2) the amount of the liability is reasonably estimable. See **Chapter 6** for a discussion of the measurement of a loss contingency.

In addition, the nonpublic entity would need to evaluate whether it has any arrangements in place with its employees that would make it responsible for its employees’ tax liability.

An entity has a legal right to seek reimbursement for the payroll tax liability (although not for income tax withholding, penalties, or interest) from employees if the IRS makes a determination to seek the withholdings from the entity. Accordingly, an entity could record an offsetting receivable from the employees for the payroll tax withholdings. However, an entity will need to assess the collectibility of such a receivable, including whether the entity has sufficient evidence of an employee’s ability to reimburse the entity for the payroll tax liability and whether the entity has the intent to collect this receivable from the employee.
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The following is an example of a disclosure that an entity may make about its repurchase of common stock from its employees when it has incurred a payroll tax liability as a result of not withholding payroll taxes:

In connection with our Series A financing, we repurchased common shares from our employees. The transaction was undertaken to provide liquidity to our employees and allows us to offer investors additional Series A shares without further dilution of the existing shareholders. While we have viewed the transaction to be a capital transaction for tax purposes, tax authorities could challenge this characterization and consider a portion of the payment to be compensation to the employees, which would require us to remit payroll tax withholdings to the tax authorities. For the probable amount of taxes and penalties that may be payable, the Company has recorded a liability of $5.0 million, which represents the low end of the range of probable amounts of payroll tax withholdings and penalties that would be payable. The ultimate payment amount could exceed the liability recorded, and we estimate that the reasonably possible range of such payment could be up to $8.0 million.

Given the complexities of this type of transaction, including the evaluation of existing tax law, entities should consult with their accounting advisers when measuring the liability under ASC 450.

For further considerations related to common-stock repurchase transactions, see Deloitte's June 6, 2018, Financial Reporting Alert.

9.3 Presentation of Net Periodic Benefit Cost Related to Defined Benefit Plans (ASU 2017-07)

In March 2017, the FASB issued ASU 2017-07, which amends the requirements in ASC 715 related to the income statement presentation of the components of net periodic benefit cost for an entity's sponsored defined benefit pension and other postretirement plans.

Under current U.S. GAAP, net benefit cost (i.e., defined benefit pension cost and postretirement benefit cost) consists of several components that reflect different aspects of an employer's financial arrangements as well as the cost of benefits earned by employees. These components are aggregated and reported net in the financial statements. In addition, there is currently no specific guidance on where in the income statement an entity should present net benefit cost.

9.3.1 Key Provisions

ASU 2017-07 requires entities to (1) disaggregate the current-service-cost component from the other components of net benefit cost (the “other components”) and present it with other current compensation costs for related employees in the income statement and (2) present the other components elsewhere in the income statement and outside of income from operations if such a subtotal is presented. The ASU also requires entities to disclose the income statement lines that contain the other components if those components are not presented on appropriately described separate lines.

Connecting the Dots

While ASU 2017-07 does not require entities to further disaggregate the other components, they may do so if they believe that the information would be helpful to financial statement users. However, entities must disclose which financial statement lines contain the disaggregated components.

In addition, only the service-cost component of net benefit cost is eligible for capitalization (e.g., as part of inventory or PP&E). This is a change from current practice, under which entities capitalize the aggregate net benefit cost when applicable.
9.3.2 Effective Date, Early Adoption, and Transition

For PBEs, the amendments in ASU 2017-07 are effective for interim and annual periods beginning after December 15, 2017. For all other entities, the amendments are effective for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019.

Early adoption is permitted as of the beginning of any annual period for which an entity's financial statements (interim or annual) have not been issued or made available for issuance (i.e., an entity should early adopt the amendments within the first interim period if it issues interim financial statements).

Entities must use (1) a retrospective transition method to adopt the requirement for separate presentation in the income statement of service costs and other components and (2) a prospective transition method to adopt the requirement to limit the capitalization (e.g., as part of inventory) of benefit costs to the service cost component. Further, entities must disclose the nature of and reason for the change in accounting principle in both the first interim and annual reporting periods in which they adopt the amendments.

ASU 2017-07 also establishes a practical expedient upon transition that permits entities to use their previously disclosed service cost and other costs from the prior years’ pension and other postretirement benefit plan footnotes in the comparative periods as appropriate estimates when retrospectively changing the presentation of these costs in the income statement. Entities that apply the practical expedient need to disclose that they did so.

For more information about ASU 2017-07, see Deloitte’s March 14, 2017, Heads Up.

9.4 Changes to Disclosure Requirements for Defined Benefit Plans (ASU 2018-14)

In August 2018, the FASB issued ASU 2018-14, which amends ASC 715 to add, remove, and clarify disclosure requirements related to defined benefit pension and other postretirement plans. The ASU’s changes related to disclosures are part of the FASB’s disclosure framework project, which the Board launched in 2014 to improve the effectiveness of disclosures in notes to financial statements.

9.4.1 Key Provisions of ASU 2018-14

9.4.1.1 Addition and Removal of Disclosure Requirements

ASU 2018-14 adds requirements for an entity to disclose the following:

- The weighted-average interest crediting rates used in the entity’s cash balance pension plans and other similar plans.
- A narrative description of the reasons for significant gains and losses affecting the benefit obligation for the period.
- An explanation of any other significant changes in the benefit obligation or plan assets that are not otherwise apparent in the other disclosures required by ASC 715.
ASU 2018-14 removes the requirements for an entity to disclose the following:

- The amounts in AOCI expected to be recognized as part of net periodic benefit cost over the next year.
- Information about plan assets to be returned to the entity, including amounts and expected timing.
- Transactions resulting from the June 2001 amendments to the Japanese Welfare Pension Insurance Law.
- Information about (1) benefits covered by related-party insurance and annuity contracts and (2) significant transactions between the plan and related parties. (Entities separately need to provide the related-party disclosures required under ASC 850.)
- For nonpublic entities with Level 3 plan assets in the fair value hierarchy measured on a recurring basis, a reconciliation of the opening balances to the closing balances. (However, those entities would still need to disclose transfers of plan assets into and out of Level 3 and any purchases of Level 3 assets by the plan.)
- For public entities, the effects of a one-percentage-point change on the assumed health care costs and the effect of this change in rates on service cost, interest cost, and the benefit obligation for postretirement health care benefits.

### 9.4.1.2 Clarification of Disclosure Requirements

ASU 2018-14 also clarifies the guidance in ASC 715-20-50-3 to require disclosure of (1) the projected benefit obligation (PBO) and fair value of plan assets for pension plans with PBOs in excess of plan assets (the same disclosure with reference to the accumulated postretirement benefit obligation rather than the PBO is required for other postretirement benefit plans) and (2) the accumulated benefit obligation (ABO) and fair value of plan assets for pension plans with ABOs in excess of plan assets.

### 9.4.2 Effective Date and Transition

For PBEs, ASU 2018-14 is effective for fiscal years ending after December 15, 2020. For all other entities, the ASU is effective for fiscal years ending after December 15, 2021. Early adoption is permitted. Entities are required to apply ASU 2018-14’s amendments on a retrospective basis.

For more information about ASU 2018-14, see Deloitte's August 29, 2018, *Heads Up*. 
10.1 Introduction
Drug development is challenging, complex, time-consuming and costly. Every year, billions of dollars are spent developing new drugs, with some studies showing that the cost of bringing an asset to market increased to record levels in 2018, even as R&D returns have fallen to the lowest level in years.\textsuperscript{1} To fund the cost of drug development, life sciences entities frequently seek external financing. Many of the financing transactions include complex terms and conditions that require a careful accounting analysis.

The SEC staff historically has focused on the classification of liabilities and equity on the balance sheet when equity instruments have redemption provisions or financial instruments possess characteristics of both liabilities and equity. For example, classification of convertible debt instruments and freestanding warrants is often scrutinized since they may contain both liability and equity components under U.S. GAAP.

In addition, prospective SEC registrants in the life sciences industry may have previously outstanding instruments with characteristics of both liabilities and equity at the time they are approaching a potential initial public offering (IPO), or life sciences entities may issue new instruments in connection with a potential IPO. Even if certain instruments are already outstanding before an IPO, it may be appropriate for an instrument to be classified outside of permanent equity in accordance with SEC rules when public financial statements are initially filed. Further, for a life sciences entity that becomes a public company, there can be other accounting consequences that did not exist while the entity was private.

10.2 Industry Issues
The discussion below highlights guidance on the accounting for financial instruments that frequently affects life sciences entities. The guidance cited is not intended to be all-inclusive or comprehensive; rather, the discussion focuses on targeted considerations related to the application of the guidance most relevant to the industry. To complete an analysis of the accounting for financial instruments, entities must consider all facts and circumstances and use significant judgment. For additional guidance on the topics highlighted below, see Deloitte’s *A Roadmap to Distinguishing Liabilities From Equity* and *A Roadmap to Accounting for Contracts on an Entity’s Own Equity*.

\textsuperscript{1} See, for example, the Deloitte Centre for Health Solutions’ ninth annual pharmaceutical study, “Embracing the Future of Work to Unlock R&D Productivity: Measuring the Return From Pharmaceutical Innovation 2018.”
10.2.1 Sequence of Decision-Making

Upon the issuance of an equity instrument, a life sciences entity should first evaluate whether the instrument meets the definition of a liability in accordance with ASC 480-10. ASC 480-10 applies to both PBEs (including SEC registrants) and private companies that are issuers of financial instruments within its scope. ASC 480-10 provides guidance on determining whether (1) certain financial instruments with both debt-like and equity-like characteristics should be accounted for “outside of equity” (i.e., as liabilities or, in some cases, assets) by the issuer and (2) SEC registrants should present certain redeemable equity instruments as temporary equity. Contracts and transactions that may require evaluation under ASC 480-10 include:

- Redeemable shares.
- Redeemable noncontrolling interests.
- Forward contracts to repurchase own shares.
- Forward contracts to sell redeemable shares.
- Written put options on own stock.
- Warrants (and written call options) on redeemable equity shares.
- Warrants on shares with deemed liquidation provisions.
- Puttable warrants on own stock.
- Equity collars.
- Share-settled debt.
- Preferred shares that are mandatorily convertible into a variable number of common shares.
- Unsettled treasury stock transactions.
- Accelerated share repurchase programs.
- Hybrid equity units.

However, ASC 480-10 does not apply to legal-form debt, which is always classified as a liability by the issuer. If the legal form of an instrument is equity, further evaluation is necessary.

ASC 480-10 applies only to items that have all of the following characteristics:

- They embody one or more obligations of the issuer. An obligation can be either unconditional or conditional. An obligation is unconditional if no condition needs to be satisfied (other than the passage of time) to trigger a duty or responsibility for the obligated party to perform. The following items are examples of unconditional obligations:
  - Mandatorily redeemable financial instruments (as defined in ASC 480-10-20).
  - Physically settled forward contracts that require the issuer to repurchase equity shares by transferring assets or a variable number of shares.
  - Preferred stock that mandatorily converts into a variable number of common shares.
An obligation is conditional if the obligated party only has a duty or responsibility to perform if a specified condition is met (e.g., the occurrence or nonoccurrence of an uncertain future event or the counterparty’s election to exercise an option). The following items are examples of conditional obligations:

- Physically settled written put options that, if exercised, could require the issuer to purchase equity shares and transfer assets.
- Physically settled forward contracts that require the issuer to purchase equity shares upon the occurrence or nonoccurrence of an event that is outside the issuer’s control.
- Net-settled forward contracts to purchase equity shares that could require the issuer to transfer cash or a variable number of equity shares to settle the contracts’ fair value if they are in a loss position.
- Net-settled written options that require the issuer to transfer assets or shares if the counterparty elects to exercise the options.

ASC 480-10 does not address the accounting for financial instruments that do not embody any obligation of the issuer. The following items are examples of such instruments:

- Outstanding equity shares that do not have any redemption or conversion provisions.
- Purchased call options that permit but do not require the issuer to purchase equity shares for cash (see ASC 480-10-55-35).
- Purchased put options that permit but do not require the issuer to sell equity shares for cash.

They meet the definition of a financial instrument. Items that qualify as financial instruments include:

- Ownership interests (e.g., common or preferred shares or interests in a partnership or limited liability company).
- Contracts to deliver cash (e.g., net-cash-settled options or forward contracts).
- Contracts to deliver shares (e.g., share-settled debt or net-share-settled options or forward contracts).
- Contracts to exchange financial instruments (e.g., physically settled written options or forward contracts that involve the exchange of equity shares for cash or another financial asset).

They meet the definition of a freestanding financial instrument (i.e., they are not features embedded in a freestanding financial instrument). ASC 480-10-20 defines a freestanding financial instrument as one that is entered into either “separately and apart from any of the entity’s other financial instruments or equity transactions” or “in conjunction with some other transaction and is legally detachable and separately exercisable.”

Their legal form is that of a share, or they could result in the receipt or delivery of shares or are indexed to an obligation to repurchase shares.
Chapter 10 — Financial Instruments

ASC 480-10 requires an instrument that has all of the above characteristics to be classified outside of equity if it falls within one of the following classes of instruments:

- **Mandatorily redeemable financial instruments** — The issuer of a financial instrument that is in the form of a share must classify the share as a liability if it embodies an unconditional obligation requiring the issuer to redeem the share by transferring assets unless redemption would occur only upon the liquidation or termination of the reporting entity. Mandatorily redeemable financial instruments include those mandatorily redeemable shares and mandatorily redeemable noncontrolling interests that do not contain any substantive conversion features.

- **Obligations to repurchase the issuer's shares (or indexed to such obligations) by transferring assets** — A financial instrument other than an outstanding share is classified as an asset or a liability if it both (1) embodies an obligation to repurchase the issuer's equity shares (or is indexed to such an obligation) and (2) requires (or may require) the issuer to settle the obligation by transferring assets. Financial instruments that meet these criteria include those forward purchase contracts and written put options on the entity's own equity shares that are either physically settled or net cash settled.

- **Certain obligations to issue a variable number of shares** — An outstanding share that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies an obligation, is classified as an asset or a liability if the issuer must or may settle the obligation by issuing a variable number of its equity shares and the obligation's monetary value is based solely or predominantly on one of the following: (1) a fixed monetary amount, (2) variations in something other than the fair value of the issuer's equity shares, or (3) variations inversely related to changes in the fair value of the issuer's equity shares. Instruments in this category include share-settled debt and those forward purchase contracts and written put options on the entity's own equity shares that are net share settled.

Financial instruments that are accounted for as assets or liabilities under ASC 480 are initially recognized at fair value, with one exception. A forward contract that requires the entity to repurchase a fixed number of its equity shares for cash is initially measured at the fair value of the shares at inception (i.e., not the fair value of the forward contract), with certain adjustments, and the offsetting entry is presented in equity (i.e., the transaction is treated as if the repurchase had already occurred with borrowed funds).

In subsequent periods, financial instruments classified as assets or liabilities under ASC 480-10 are remeasured at their then-current fair value, and changes in fair value are recorded in earnings, with two exceptions. ASC 480-10-35-3 states that physically settled forward contracts to repurchase “a fixed number of the issuer's equity shares [for] cash and mandatorily redeemable financial instruments [are] measured subsequently in either of the following ways,” as applicable:

a. If both the amount to be paid and the settlement date are fixed, those instruments shall be measured subsequently at the present value of the amount to be paid at settlement, accruing interest cost using the rate implicit at inception.

b. If either the amount to be paid or the settlement date varies based on specified conditions, those instruments shall be measured subsequently at the amount of cash that would be paid under the conditions specified in the contract if settlement occurred at the reporting date, recognizing the resulting change in that amount from the previous reporting date as interest cost.
The fact that an instrument does not need to be classified as an asset or a liability under ASC 480-10 does not necessarily mean that it qualifies for equity classification. To determine whether an instrument qualifies for classification in equity in whole or in part, an entity must also consider other GAAP (e.g., ASC 470-20, ASC 815-10, ASC 815-15, and ASC 815-40). Further, under ASC 480-10-599-3A, an entity that is subject to SEC guidance should consider whether an equity-classified instrument must be classified outside of permanent equity.

Once an issuer has determined that the appropriate balance sheet classification for the equity instrument is liability, temporary equity, or permanent equity, the issuer should further evaluate the instrument to identify any embedded features that may need to be bifurcated and accounted for separately as derivative instruments.

The sections below outline some of the more common types of securities that life sciences entities issue, together with the related accounting considerations.

### 10.2.2 Redeemable Equity Securities

The SEC staff believes that redeemable equity securities are significantly different from conventional equity capital because such securities possess characteristics similar to debt as a result of the redemption obligation attached to the securities. The guidance in ASC 480-10-S99-3A requires instruments to be classified outside of permanent equity in “temporary equity” if they are redeemable (1) at a fixed or determinable price on a fixed or determinable date, (2) at the option of the holder, or (3) upon the occurrence of an event that is not solely within the issuer’s control. To determine the appropriate classification, SEC registrants must evaluate all facts and circumstances related to events that could trigger redemption of the securities. Issuers should evaluate whether equity instruments that do not meet the definition of a liability under ASC 480-10 nevertheless must be presented outside of permanent equity because of any of these provisions.

Because only public entities are required to present certain equity instruments as temporary equity (sometimes referred to as mezzanine equity) instead of permanent equity, the SEC staff frequently comments on this topic during the IPO process.

#### 10.2.2.1 Mandatorily Redeemable Equity Securities

ASC 480 requires mandatorily redeemable securities to be reported as liabilities. Other redeemable equity securities are classified outside of shareholders' equity in “temporary equity” under the SEC staff's guidance. More specifically, for a redeemable equity security to be classified as a liability under ASC 480, it must be certain that redemption will occur; redeemable equity securities whose redemption is not certain are classified as temporary equity under the SEC staff’s guidance. Therefore, mandatorily redeemable preferred securities that have substantive conversion options at issuance would not be considered liabilities under ASC 480 even though such securities are called mandatorily redeemable convertible securities. This is because as long as the conversion option is substantive, it is not certain that redemption will occur. If the issuer does not have control over any event that could trigger redemption of the security, the security would be classified as temporary equity under the SEC staff's guidance.

The treatment of the return paid to the holder of redeemable securities differs depending on whether the securities are classified as liabilities or as temporary equity. For securities classified as liabilities under ASC 480, such a return is treated as an expense. For redeemable securities classified as temporary equity, such a return is treated as a dividend.

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2 See ASC 480-10-599-3A-5.
Connecting the Dots

In general, an entity should first apply the guidance in ASC 480 when determining the appropriate presentation of redeemable securities on the balance sheet. If the securities are not classified as liabilities under ASC 480, the entity should examine them under SEC staff guidance to determine whether it is appropriate to classify them as temporary equity. In addition, registrants should be familiar with the SEC staff's views on the applicability of its guidance in certain situations. For example, if redemption is required only upon the liquidation of the reporting entity, an instrument is not considered redeemable. This situation and others are described in ASC 480-10-S99-3A.

10.2.2.2 Redeemable Securities Whose Redemption Is Outside the Issuer's Control

The analysis of whether a security's redemption is not solely within the issuer's control could be complicated depending on the triggering events associated with redemption. The SEC staff believes that the issuer should evaluate each triggering event separately, along with relevant facts and circumstances, to determine whether it is outside the issuer's control. If any triggering events are outside the issuer's control, the security should be classified outside of permanent equity regardless of the probability of such events.3 ASC 480-10-S99-3A-6 through S99-3A-9 provide examples of events that are outside the issuer's control.

Connecting the Dots

Nonpublic life sciences entities, including start-ups and other entities financed by private equity or venture capital firms, often have one or more series of convertible preferred stock issued and outstanding. In evaluating the appropriate classification in the statement of financial condition of convertible preferred stock, a life sciences entity should first consider whether the convertible preferred stock represents a mandatorily redeemable financial instrument that is required to be classified as a liability under ASC 480-10-25-4. If a preferred stock instrument contains an embedded conversion option that is considered a substantive feature as of the issuance date,4 the convertible preferred stock instrument would not qualify as a mandatorily redeemable financial instrument.5

When convertible preferred stock is not required to be classified as a liability, life sciences entities should consider the SEC staff's guidance in ASC 480-10-S99-3A to determine whether it is appropriate to classify the convertible preferred stock in permanent equity. Convertible preferred stock should be classified in temporary equity if the instrument contains (1) a stated redemption feature that allows or requires the holder to put the security to the issuer on a specified date (or dates) or (2) a stated redemption feature that allows the holder to put the security to the issuer upon the occurrence of a specified event that is not solely within the issuer's control. Therefore, when the holders of convertible preferred stock have control over the entity, the following convertible preferred stock instruments must also be classified in temporary equity:

- Convertible preferred stock that contains a stated redemption feature that allows the issuer to call the security on a specified date (or dates).

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3 See footnote 2.
4 A conversion feature that results in settlement of the instrument through the issuance of a variable number of shares of common stock equal to a fixed monetary amount is equivalent to “share-settled” debt and would not represent a substantive conversion option. For additional guidance, see ASC 470-20-40-5 through 40-10.
5 See ASC 480-10-55-11 and 55-12.
• Convertible preferred stock that contains a stated redemption feature that allows the holder to put the security to the issuer upon the occurrence of a specified event that can be controlled by the vote of the entity’s stockholders or by actions of the entity's board of directors.

Even if a convertible preferred stock instrument does not contain a stated redemption feature (i.e., a stated call option or a stated put option), the instrument's liquidation provisions must still be considered, including whether those provisions are considered “ordinary liquidation” or “deemed liquidation” provisions. An ordinary liquidation provision does not trigger the requirement to classify the convertible preferred equity in temporary equity, a deemed liquidation provision will typically trigger the requirement to classify the convertible preferred equity in temporary equity. See Chapter 9 of Deloitte’s A Roadmap to Distinguishing Liabilities From Equity for additional guidance.

10.2.2.3 Measurement of Instruments Classified in Temporary Equity

If an instrument classified in temporary equity is currently redeemable, it should be adjusted to its maximum redemption amount as of the balance sheet date. However, if an instrument classified in temporary equity is not currently redeemable and the registrant determines that its redeemability is not probable, subsequent adjustment of the carrying amount is not necessary until it is probable that the security will become redeemable.6

10.2.3 Preferred Stock That Is Nonredeemable or Is Redeemable Solely at the Option of the Issuer

When securities are not redeemable or are redeemable solely at the option of the issuer, those securities are generally classified in permanent equity on the balance sheet. All relevant facts and circumstances should be considered in the determination of whether the redemption is solely at the option of the issuer.7 The SEC staff often emphasizes that issuers should examine the redemption provision of all securities classified in permanent equity to ensure their proper classification. For example, an instrument may not be redeemable for cash but may be convertible into another class of equity. Unless management can assert that it has the ability to settle the conversion with shares, it could be forced to redeem the instrument for cash, resulting in classification of that instrument outside of permanent equity. In addition, according to its terms, a security may be redeemable solely at the option of the issuer; however, if the holder of the security controls the issuer's board of directors, that security would be considered redeemable at the option of the holder and would be classified as temporary equity.8

If classification of securities as temporary equity is no longer appropriate because of a change in the redemption feature, the outstanding carrying amount of securities should be reclassified as permanent equity on the date of the event that causes the reclassification.

Even if the entire instrument should be classified in permanent equity under ASC 480-10-S99-3A, the issuer may be required to perform further analysis to determine whether the equity instrument contains embedded derivatives that must be bifurcated and accounted for separately as derivative instruments in accordance with ASC 815-15.

7 See ASC 480-10-S99-3A-11.
8 See ASC 480-10-S99-3A-7.
10.2.4 Conversion Features of Preferred Stock and Debt

As discussed in Section 10.2.6.2, an issuer should perform an evaluation under ASC 815 to determine whether contracts, such as those involving convertible preferred stock or convertible debt, contain embedded equity derivatives that may need to be bifurcated and accounted for separately from the host contract under ASC 815’s bifurcation requirements. If an embedded conversion feature does not need to be bifurcated from the hybrid instrument as an embedded derivative, but the convertible instrument contains beneficial conversion features (BCFs) or may be settled entirely or partially in cash, the instrument may need to be separated into a liability component and an equity component. After concluding that a conversion option does not need to be bifurcated under ASC 815, an issuer should consider whether the cash conversion guidance in ASC 470-20 applies. If the hybrid instrument is not within the scope of the cash conversion guidance, the issuer should consider the BCF guidance in ASC 470-20. Both the cash conversion guidance and the BCF guidance in ASC 470-20 are discussed below.

10.2.4.1 Cash Conversion Features

As discussed above, an issuer should evaluate whether a convertible instrument must be accounted for under the cash conversion guidance in ASC 470-20 if the conversion feature did not need to be bifurcated in accordance with ASC 815-15. The cash conversion guidance applies only to convertible debt that may be settled partially or fully in cash upon conversion. Typically, the convertible debt will allow the issuer to settle the par amount in cash and to deliver shares with a fair value equal to the intrinsic value of the conversion option.

Issuers of both convertible debt and convertible preferred stock should consider this guidance; however, since the guidance applies only to convertible debt, convertible preferred stock is considered only if the preferred stock is mandatorily redeemable and classified as a liability under ASC 480-10. Equity-classified convertible preferred stock (including preferred stock classified in temporary equity) is outside the scope of the cash conversion guidance in ASC 470-20. In general, mandatorily convertible preferred stock is also outside the scope of the cash conversion guidance in ASC 470-20 because it will be classified as a liability only if (1) the conversion option is not considered substantive at issuance or (2) the issuer, upon conversion, had to settle a portion of that conversion in cash (the issuance of cash for fractional shares can be ignored).

A convertible debt instrument would not be within the scope of the ASC 470-20 cash conversion guidance if cash settlement would occur only when all other holders of the underlying shares also receive cash. Further, convertible debt that provides for the settlement of fractional shares in cash upon conversion would not be within the scope of the cash conversion guidance.

The debt and equity components of instruments within the scope of the cash conversion guidance must be accounted for separately. To account for those components, the issuer first determines the fair value of a similar liability without the conversion option, which represents the liability (debt) portion of the instrument. The remainder of any proceeds allocated to the convertible instrument is allocated to the conversion (equity) portion. The method used to determine the value of a cash conversion feature (i.e., based on the fair value of the debt component) differs from the approach discussed below to determine the value of a BCF (i.e., based on the intrinsic value of the equity component).
10.2.4.2  Beneficial Conversion Features

ASC 470-20-20 defines a BCF as a “nondetachable conversion feature that is in the money at the commitment date.” If the conversion price embedded in preferred stock or debt is lower than the fair value of the stock into which the preferred stock or debt is convertible as of the commitment date and the conversion feature does not need to be bifurcated as an embedded derivative, the conversion feature may be “beneficial.” If the conversion feature is beneficial, the effect of the difference between the conversion price and the fair value of the stock should reduce the carrying amount of the convertible instrument and be recognized in equity.

Connecting the Dots

In determining whether a BCF exists, an entity should consider the “effective conversion price” that an investor effectively would pay for a share upon conversion. For instance, if convertible debt was issued at a discount or a portion of the proceeds was allocated to detachable warrants, an entity would calculate the effective conversion price of the debt by using the amount allocated to the debt for accounting purposes.

The SEC staff frequently seeks to identify embedded BCFs by analyzing the conversion price in convertible instruments issued within one year of an IPO filing. When the conversion price is lower than the IPO price, the SEC staff may require a prospective registrant to recognize an expense related to a BCF and may sometimes require it to use the IPO price as a base in measuring the BCF. If the prospective registrant believes that the conversion price represented the stock’s fair value at the time the instrument was issued, it should be prepared to present sufficient evidence to support its assertion.

Connecting the Dots

Identifying a BCF can be complex because it is directly related to the appropriateness of the fair value assigned to the underlying stock when that stock is not actively traded.

Once an entity identifies a BCF, the entity would recognize that embedded feature separately at issuance by allocating a portion of the proceeds equal to the intrinsic value of the embedded feature to additional paid-in capital. If a BCF is contingent on the occurrence of a future event such as an IPO, an entity would measure the BCF in the same way but would not recognize it in earnings until the contingency is resolved.

10.2.5  Accelerated Share Repurchase Programs

Several life sciences companies have considered or executed accelerated share repurchase (ASR) programs in recent years. As described in ASC 505-30-25-5, an ASR program is “a combination of transactions that permits an entity to repurchase a targeted number of shares immediately with the final repurchase price of those shares determined by an average market price over a fixed period of time. An accelerated share repurchase program is intended to combine the immediate share retirement benefits of a tender offer with the market impact and pricing benefits of a disciplined daily open market stock repurchase program.”

ASC 505-30-25 contains unit-of-account guidance for ASR programs. Under ASC 505-30-25-6, an entity accounts for an ASR as two separate units of account: a treasury stock repurchase and a separate forward contract on the entity’s shares. An entity should analyze the treasury stock repurchase and forward contract separately to determine how to account for each unit of account. Because ASC 815-40 contains an exception for financial instruments that are within the scope of ASC 480-10, the entity should determine whether one or both units of account are within the scope of ASC 480-10 before considering whether ASC 815-40 applies.
The terms of ASRs vary. In a traditional ASR, an entity (1) repurchases a targeted number of its own shares at the current stock price immediately for cash and (2) simultaneously enters into a net-share-settled forward sale of the same number of shares indexed to the average stock market price over the contract period. Economically, the forward serves as a true-up mechanism for adjusting the price ultimately paid for the shares purchased. Its purpose is to reduce the number of outstanding shares immediately at a repurchase price that on a combined basis reflects the average stock market price over an extended period (e.g., the volume-weighted average price on each trading day during the contract period). On a combined basis, the initial share repurchase and the forward sale put the issuer in an economic position similar to that of having conducted a series of open market purchases of its own stock over a specified period.

Example 10-1

ASR Analysis

An entity makes an up-front cash payment and receives a specific number of shares from the counterparty (usually an investment bank). Upon settlement of the forward contract (typically within three to six months), the entity either (1) pays the counterparty an amount equal to any excess of the volume-weighted average daily market price (VWAP) of the entity's shares over the initial purchase price or (2) receives from the counterparty an amount equal to any excess of the initial purchase price over the VWAP. Often, the entity can choose to settle the forward contract with the counterparty in either cash or a variable number of shares. Under ASC 505-30, this transaction is analyzed as two units of account: a treasury stock repurchase and a net settled forward contract to sell the entity's stock over the contract period.

In practice, the settlement of the treasury stock repurchase often takes place one or a few days after the execution of the ASR (e.g., the initial share delivery date may be three business days after the transaction date), at which time the issuer pays cash and receives an initial number of shares. In such cases, the obligation to repurchase shares in exchange for cash is classified as a liability under ASC 480-10-25-8 (see Chapter 5 of Deloitte's A Roadmap to Distinguishing Liabilities From Equity) during the period between the ASR transaction date and the settlement date of the treasury stock repurchase (sometimes described as the “initial share delivery date” or the “prepayment date”). Note that in some ASR transactions, the payment of cash in the treasury stock repurchase occurs before the receipt of the initial shares, in which case ASC 480-10 may cease to apply once the obligation to pay cash has been settled.

In evaluating whether the forward component of an ASR is within the scope of ASC 480-10, the issuer should consider whether it embodies an obligation to transfer assets or a variable number of shares that meet the criteria in ASC 480-10-25-8 or ASC 480-10-25-14 (see Chapters 5 and 6 of Deloitte’s A Roadmap to Distinguishing Liabilities From Equity). Usually, an issuer is not required to classify as a liability under ASC 480-10 the forward contract component in a traditional ASR because it does not embody an obligation to repurchase shares for assets and does not involve an obligation to deliver a variable number of shares with a monetary value that moves inversely with — or is based on something other than — the price of the issuer's stock. However, an issuer cannot assume that the forward contract component of an ASR is outside the scope of ASC 480-10 without analyzing its specific terms and features.
In some ASR transactions, a portion of the prepayment amount on the initial share delivery date represents a premium paid by the issuer to increase the forward sale price that the issuer will receive in the forward component of the transaction (relative to an at-market forward) rather than a payment for the shares to be received in the initial treasury stock repurchase. For example, the issuer may apply 20 percent of the prepayment amount to the forward component to reduce the likelihood that the forward component will ever dilute earnings per share. In that case, the issuer may be required to account for the forward component as an asset or a liability under ASC 480-10-25-8 in the period between the transaction date and the initial share delivery date if the forward component permits net share settlement. This is because the forward component embodies an obligation to pay cash (on the initial share delivery date) to repurchase shares (the issuer will receive shares on the forward settlement date if the stock price is less than the forward price).

If the forward component is outside the scope of ASC 480-10, the issuer considers the guidance in ASC 815-40 when it determines whether the forward should be accounted for as an asset or liability. The terms of an ASR often include rights for the counterparty to end the ASR early upon termination events defined by reference to ISDA’s equity derivatives definitions (e.g., merger events, tender offers, nationalization, insolvency, delisting, change in law, failure to deliver, loss of stock borrowings, increased cost of stock borrowings, extraordinary dividends). Further, the contractual provisions often specify or permit the counterparty to make adjustments to the settlement terms upon the occurrence of such events (e.g., calculation agent adjustments, cancellation, and payment) and might require the entity to settle the contract net in cash. In evaluating an ASR’s forward-contract component under ASC 815-40, therefore, the entity should be mindful of the need to assess such terms under the indexation guidance and other equity classification conditions in ASC 815-40.

**Example 10-2**

On December 30, an issuer enters into an ASR transaction that requires it to transfer a fixed amount of cash (a prepayment amount of $500 million) in exchange for a fixed number of its common shares (10 million initial shares) on the initial share delivery date (January 2). The issuer will either deliver or receive shares on the transaction’s final settlement date (March 31). If the VWAP of the issuer’s common shares exceeds $50, the issuer will deliver shares; if the VWAP is less than $50, the issuer will receive shares. The number of shares that will be received or delivered is calculated as the prepayment amount ($500 million) divided by the VWAP over the contract period less the initial shares (10 million) already delivered.

In these circumstances, the treasury stock repurchase must be accounted for as a liability under ASC 480-10-25-8. In accordance with ASC 480-10-30-3, the issuer recognizes the liability on the ASR transaction date, which was initially measured “at the fair value of the shares at inception, adjusted for any consideration or unstated rights or privileges.” Simultaneously, in accordance with ASC 480-10-30-5, equity is “reduced by an amount equal to the fair value of the shares at inception.” Because under ASC 480-10-35-3(a) both the amount to be paid — $500 million — and the settlement date — January 2 — are fixed, the liability is measured at the present value of the amount to be paid at settlement — $500 million — with interest cost accruing at the rate implicit at inception during the period from the transaction date to the initial share delivery date. (Further, if any part of the prepayment amount represents a premium payment for the forward component of the ASR transaction, that portion would be accounted for separately as a liability measured at fair value under ASC 480-10-35-1, ASC 480-10-35-4A, or ASC 480-10-35-5 between the transaction date and the initial share delivery date, as discussed above.)

On the initial share delivery date, the liability for the treasury stock repurchase is extinguished by delivery of the prepayment amount. After the initial share delivery date, the transaction is outside the scope of ASC 480-10 and is therefore evaluated under other GAAP (including ASC 815-10 and ASC 815-40).
10.2.6 Derivatives

Common financing arrangements issued by life sciences entities in the form of debt or equity capital may be considered to be or may contain equity derivatives (i.e., equity derivatives may be freestanding or embedded). Examples of common equity derivatives are stock warrants, stock options, and forward contracts to buy or sell an entity's shares. Equity derivatives may be classified as liabilities (or, in some cases, as assets) and measured at fair value on the balance sheet, with changes in fair value recognized in earnings. It is important to be aware of these instruments, how they are accounted for, and subsequent events that could affect such accounting. Sometimes, the measurement attribute for such instruments could be fair value as a result of an IPO or subsequent financing.

The first step in the analysis is to consider whether the equity derivative is a freestanding instrument or whether it is embedded in another instrument. If the instrument is freestanding, the guidance in ASC 815-40 will govern the classification and measurement of the instrument unless the instrument is a liability within the scope of ASC 480, as discussed above. It is important to note that the guidance in ASC 815-40 is applicable to freestanding contracts on an entity's own equity regardless of whether those contracts meet the definition of a derivative in ASC 815-10. Contracts on an entity's own equity may need to be classified as assets and liabilities (and remeasured at fair value every reporting period) even if they are not considered derivatives within the scope of ASC 815-10. Also, contracts that meet the conditions for classification in equity under ASC 815-40 are excluded from the scope of ASC 815-10 even if they meet the definition of a derivative.

If an equity derivative is embedded in a hybrid instrument, the guidance in ASC 815-40 will be applicable only to embedded features that meet the definition of a derivative and meet the other criteria for bifurcation. That is, if an embedded equity derivative is not clearly and closely related to the host contract, the hybrid instrument is not remeasured at fair value with changes in fair value recognized in earnings; and if the embedded derivative meets the definition of a derivative in ASC 815-10, the guidance in ASC 815-40 will be relevant in the determination of whether the equity derivative needs to be bifurcated because of the scope exception in ASC 815-10, as discussed above.

10.2.6.1 ASC 815-40 — Contracts on an Entity’s Own Equity

ASC 815-40 provides guidance on whether an instrument or embedded feature is indexed to an entity's own stock and whether it can be settled in the entity's shares. The analysis under ASC 815-40 can be complex; in performing this analysis, an entity often must consult with its legal counsel regarding the various terms associated with the contract. The SEC staff has noted common questions related to applying the guidance in ASC 815-40, including the following:

- Cash settlement provisions.
- Requirement to settle in registered shares.
- Insufficient number of authorized but unissued shares.
- No limit on the number of shares to be delivered.
- Incorrect conclusion regarding whether the instrument is indexed to an entity's own stock.

In general, a contract on an entity's own equity can be classified in equity (and not remeasured while it is classified in equity) as long as it is considered to be indexed to the entity's own stock and the issuer has the ability to settle the contract by issuing its own shares under all scenarios. This determination requires an evaluation of all events that could change the settlement value (e.g., adjustments to strike price) and all events that would affect the form of settlement. For additional guidance on ASC 815-40, see Deloitte's *A Roadmap to Accounting for Contracts on an Entity's Own Equity*.
For example, as the result of a provision to adjust the conversion price (other than a standard antidilution provision that applies to all shareholders), an entity may consider an instrument not to be indexed to the issuer's own stock. This type of situation has often been problematic for entities that provide certain investors with price protection by adjusting the strike price if there is a subsequent round of equity or convertible instrument financing at a strike price that is lower than theirs. Under a provision that triggers such price protection (a “down-round provision”), the strike price would usually be adjusted to the strike price of the subsequent transaction. As a result, an instrument or embedded derivative would be accounted for as an asset or liability. However, in July 2017, the FASB issued ASU 2017-11, which makes limited changes to the guidance in ASC 815-40. (For a discussion of other new guidance on financial instruments, see Section 10.3.)

Before an issuer adopts ASU 2017-11, a contract (or embedded equity conversion feature) that contains a down-round provision does not qualify as equity because such an arrangement precludes a conclusion that the contract is indexed to the entity's own stock under ASC 815-40-15. Therefore, freestanding contracts on an entity's own equity that contain a down-round feature have been accounted for at fair value, with changes in fair value recognized in earnings. Similarly, embedded equity conversion features containing down-round provisions have been separated and accounted for as derivative instruments at fair value when the bifurcation criteria in ASC 815-15 have been met.

ASU 2017-11 applies to issuers of financial instruments with down-round features. It amends (1) the classification of many of such instruments as liabilities by revising the guidance in ASC 815 on the evaluation of whether instruments with down-round provisions may meet the conditions to be considered indexed to the issuer's own equity and (2) the guidance on recognition and measurement of the value transferred upon the triggering of a down-round feature for equity-classified instruments by revising ASC 260.

For PBEs, ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual reporting periods. For all other entities, the ASU is effective for annual reporting periods beginning after December 15, 2019, and interim periods within annual reporting periods beginning after December 15, 2020. Early adoption is permitted in any interim or annual period for which financial statements have not yet been issued or have not been made available for issuance.

For additional details, see Deloitte's July 21, 2017, *Heads Up.*

10.2.6.2 Considerations Related to Embedded Derivatives

In addition to the considerations related to freestanding instruments (e.g., warrants or stock options) under ASC 815, an entity should evaluate whether other contracts, such as those involving preferred stock or convertible debt, contain embedded equity derivatives that may need to be bifurcated and accounted for separately from the host contract under ASC 815’s bifurcation requirements. A reporting entity identifies the terms of each embedded feature on the basis of the feature’s economic payoff profile (underlying) rather than on the basis of how the feature has been formally documented. In identifying the embedded features, the entity should consider all terms of the convertible instrument. Common examples of embedded features include conversion options and redemption provisions.

Although there is no explicit guidance under U.S. GAAP on how to determine the unit of accounting for embedded features in a hybrid instrument, the approach described herein is commonly applied. Under the payoff-profile approach, each embedded derivative feature in a hybrid instrument is defined on the basis of the monetary or economic value that the feature conveys to the instrument’s counterparty upon settlement. This approach is consistent with the definition of an embedded derivative in ASC 815-15-20, which focuses on the effect of an implicit or explicit term on the cash flows or values of other exchanges required under a contract.
An identified embedded feature generally\(^{10}\) must be bifurcated and accounted for separately from the host contract if the following three conditions are met:

- The embedded feature is not clearly and closely related to the host contract.
- The host instrument (e.g., preferred stock or debt) is not remeasured at fair value, with changes in fair value recognized in earnings, under other applicable GAAP.
- A separate instrument with the same terms as the embedded feature meets the definition of a derivative instrument under ASC 815-10.\(^{11}\)

### 10.2.6.2.1 Clearly and Closely Related to the Host Contract

#### 10.2.6.2.1.1 Determining the Nature of the Host Contract

When determining whether the embedded feature being analyzed is clearly and closely related to the host contract, an entity must first decide whether the nature of the host contract is more debt-like or equity-like. ASU 2014-16, issued in November 2014, clarifies that the only acceptable method for determining the nature of the host contract in a hybrid instrument issued in the form of a share is a method commonly referred to as the “whole-instrument” approach. Under the whole-instrument approach, the nature of the host contract is the same for each embedded feature being analyzed. Determining the nature of the host contract under the whole-instrument approach involves the following steps:

- Identify all of the hybrid financial instrument's stated and implied substantive terms and features.
- Determine whether the identified terms and features are more debt-like or equity-like.
- Identify the relative weight of the identified terms and features “on the basis of the relevant facts and circumstances.”\(^{12}\)

Further, ASC 815-15-25-17A states, in part:

> In evaluating the stated and implied substantive terms and features, the existence or omission of any single term or feature does not necessarily determine the economic characteristics and risks of the host contract. Although an individual term or feature may weigh more heavily in the evaluation on the basis of the facts and circumstances, an entity should use judgment based on an evaluation of all of the relevant terms and features. For example, an entity shall not presume that the presence of a fixed-price, noncontingent redemption option held by the investor in a convertible preferred stock contract, in and of itself, determines whether the nature of the host contract is more akin to a debt instrument or more akin to an equity instrument. [Emphasis added]

If a reporting entity is still unclear about the nature of the host contract after performing this analysis, it should consider the anticipated outcome for the holder of the hybrid financial instrument in reaching its final conclusion. Given the complexity of determining the nature of a host contract of a hybrid instrument with both conversion and redemption features, entities are encouraged to consult with their accounting advisers.

The method described above for determining the nature of the host contract applies only to hybrid instruments issued in the form of a share. A legal-form debt instrument will typically be considered to be a debt host contract.

\(^{10}\) Subject to the scope exceptions in ASC 815-10.

\(^{11}\) See ASC 815-10-15-83.

\(^{12}\) See ASC 815-15-25-17C.
10.2.6.2.1.2 Determining Whether the Feature Is Clearly and Closely Related to the Host Contract

Once the reporting entity has determined the nature of the host contract, it should, in accordance with ASC 815-15-25-1(a), evaluate each embedded feature separately to determine whether the economic characteristics and risks of the embedded feature are clearly and closely related to those of the host contract. If the embedded feature is clearly and closely related to the host contract, the embedded feature should not be bifurcated. If the embedded feature is not clearly and closely related to the host contract, the reporting entity must analyze the other two conditions described above to determine whether bifurcation of the embedded feature is required.

Commonly identified embedded features that an entity would evaluate to determine whether they are clearly and closely related to a debt or equity host contract include the following:

- **Redemption features** — A redemption feature enables the holder to receive cash to settle the equity instrument. A redemption feature may be held by the issuer or the holder and may be exercisable upon the occurrence of certain events or at any time. If an equity host contract has a redemption feature, the redemption is explicitly not considered clearly and closely related to that contract in accordance with ASC 815-15-25-20. Therefore, in such cases, an entity would need to perform additional analysis to determine whether it is required to bifurcate the redemption feature.

  Under ASC 815-15-25-42, if a debt host contract has a redemption feature, an entity must perform a four-step test to determine whether the redemption feature is clearly and closely related to the debt host.

- **Conversion features** — Conversion features enable an entity to convert an existing instrument into another form of the entity's equity (e.g., convertible preferred stock, convertible debt). ASC 815-15-25-16 indicates that a conversion feature in an equity host contract would be clearly and closely related to the equity host contract since it provides the holder with another residual interest in the same entity. Accordingly, a conversion feature in an equity host contract would not be bifurcated and accounted for separately as a derivative instrument.

  However, ASC 815-15-25-51 indicates that a conversion option in a debt host contract is not clearly and closely related to the contract. Therefore, the entity would have to perform further analysis to determine whether the other bifurcation criteria are met.

- **Changing interest/dividend rates** — Contracts may include provisions under which stated interest or dividend rates increase or decrease as a result of the occurrence or nonoccurrence of specific events. An embedded derivative that resets the interest rate of a debt host contract (i.e., a debt instrument or an equity instrument that was determined to represent a debt host) is generally clearly and closely related to the debt host if it is based on changes in interest rates, the issuer's creditworthiness, or inflation. However, if, for example, an entity’s bonds include a provision under which the interest rate must be reset to a different rate if an unrelated party’s credit rating is downgraded at any time during the term of the bonds, the reset feature is not clearly and closely related to the debt host. An embedded derivative that changes an instrument's interest rate because of changes to the rate of inflation in the economic environment for the currency in which a debt instrument is denominated would be considered clearly and closely related to the debt host. Further, changes to an interest rate based on changes in an entity's operating performance (e.g., EBITDA) may be considered clearly and closely related to the debt host if the operating performance metric is related to the entity's creditworthiness.

Such interest rate reset provisions are generally not considered clearly and closely related to an equity host, however.

10.2.6.2.2 Separate Instrument With Same Terms Meets the Definition of a Derivative

An embedded equity derivative (e.g., a conversion option) that meets the first two conditions outlined above for bifurcating embedded equity derivatives would require further evaluation for an entity to determine whether the embedded feature should be separately accounted for as a derivative under ASC 815-10. ASC 815-10-15-83 defines a derivative as a financial instrument or other contract that (1) has an underlying as well as a notional amount or payment provision, (2) requires little or no initial net investment, and (3) can be net settled.

Equity instruments will generally meet the first and second criteria in the definition of a derivative but may not meet the third. For instance, a contract in a nonpublic entity’s own stock (e.g., a warrant or stock option) may not qualify as a derivative because the entity’s equity shares are not publicly traded. In such cases, unless the contract provides for net share settlement or cash settlement, the contract generally would not meet the net settlement criterion because the equity shares would not be readily convertible to cash. However, upon an IPO, the entity would need to reevaluate the contract under ASC 815 to determine whether the contract is or contains an accounting derivative now that the entity’s shares are publicly traded. If the post-IPO shares or an embedded conversion feature is readily convertible to cash, the net settlement criterion would be met, resulting in an accounting derivative that may need to be recognized unless it qualifies for a scope exception to derivative accounting (discussed further below).

For example, a warrant to acquire common-stock shares that explicitly permits net settlement (e.g., cashless exercise) would meet the net settlement criterion. However, a warrant to acquire common-stock shares of a nonpublic entity for which gross exercise is required (i.e., the warrant holder pays the exercise price in cash to acquire common shares) would generally not meet the net settlement criterion since the contract would be settled in shares that are not readily convertible to cash. If that nonpublic entity went public, however, the warrant that previously did not meet the net settlement criterion might now satisfy the criterion since common-stock shares of a publicly traded entity are generally readily convertible to cash.

A contract that meets the definition of a derivative under the above criteria may not need to be accounted for as a derivative if it qualifies for any of the scope exceptions in ASC 815-10-15-13. One of these scope exceptions involves contracts on an entity’s own equity. Generally, the value of an equity derivative is linked to the entity’s own stock (i.e., the underlying of the derivative). If the derivative is indexed to the entity’s own stock and would not require the entity to settle the derivative by paying cash or other assets, it would qualify for classification as equity and be outside of the scope of ASC 815.

Some equity derivatives may qualify for the scope exception in ASC 815-10-15-74 for certain contracts indexed to the company’s own stock. If this scope exception applies, such equity derivatives would not have to be bifurcated.

However, an embedded feature that meets the definition of a derivative and does not qualify for an explicit scope exception would need to be bifurcated from the host instrument and accounted for separately as a derivative (if the other two conditions for bifurcation are also met). A bifurcated derivative (e.g., a conversion feature) would be measured initially and subsequently at fair value, with changes in fair value recognized in earnings.
The accounting for convertible debt instruments and convertible preferred stocks is complex, and the SEC staff frequently asks about the classification of such instruments in entities’ registration statements. The flowchart below illustrates the multistep evaluation that entities are required to perform for any hybrid instrument with a conversion feature.

**10.3 New Accounting Standards**

**10.3.1 Classification and Measurement (ASU 2016-01)**

**10.3.1.1 Background**

ASU 2016-01 amends the guidance on the classification and measurement of financial instruments. The amendments contain changes related to the following:

- Accounting for equity investments (apart from those that are accounted for under the equity method or those that are consolidated).
- Recognition of changes in fair value attributable to changes in instrument-specific credit risk for financial liabilities for which the fair value option has been elected.
- Determining the valuation allowance for DTAs related to available-for-sale (AFS) debt securities.
- Disclosure requirements for financial assets and financial liabilities.

For PBEs, the new standard is effective for fiscal years beginning after December 15, 2017, including interim periods therein. For all other entities, the standard is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption of certain of the standard’s provisions is permitted for all entities. Non-PBEs are permitted to adopt the standard in accordance with the effective date for PBEs. For more information about ASU 2016-01, see Deloitte’s January 12, 2016, Heads Up.

**10.3.1.2 Classification and Measurement of Equity Investments**

The amendments in ASU 2016-01 will require entities to carry all investments in equity securities at fair value, with changes in fair value recorded through earnings, unless the equity investments are accounted for under the equity method or are consolidated. For equity investments that do not have a readily determinable fair value, the guidance will permit a measurement alternative under which the equity investment would be measured at cost less impairment, if any, plus or minus observable price changes in orderly transactions. This measurement alternative would not be available to reporting entities that are investment companies, broker-dealers in securities, or postretirement benefit plans.
An entity that has elected the measurement alternative for equity investments that do not have a readily determinable fair value is required to assess whether the equity investment is impaired by qualitatively considering the indicators described in ASC 321-10-35-3. If, on the basis of the qualitative assessment, the equity investment is impaired, an entity would be required to record an impairment equal to the amount by which the carrying value exceeds fair value. The entity should no longer evaluate whether such impairment is other than temporary.

**Connecting the Dots**

Before the adoption of ASU 2016-01, marketable equity securities other than equity method investments or those that result in consolidation of the investee are classified as either (1) held for trading, with changes in fair value recognized in earnings, or (2) AFS, with changes in fair value recognized in OCI. Further, nonmarketable equity securities for which the fair value cannot be readily determined generally would be measured at cost (less impairment) unless the fair value option is elected. Under ASU 2016-01, since equity securities can no longer be accounted for as AFS, entities holding such investments could see more volatility in earnings. Entities’ application of the measurement alternative to investments without readily determinable fair values may reduce such earnings volatility, but this alternative is not available to broker-dealers.

**10.3.1.3 Changes in Fair Value of a Liability Attributed to Changes in Instrument-Specific Credit Risk**

For financial liabilities (excluding derivative instruments) for which the fair value option has been elected, the amendments in ASU 2016-01 will require an entity to separately recognize in OCI any changes in fair value associated with instrument-specific credit risk. The guidance indicates that the portion of the total change in fair value that exceeds the amount resulting from a change in a base market risk (such as a risk-free interest rate) may be attributable to instrument-specific credit risk, but it also acknowledges that there may be other methods that an entity can use to determine instrument-specific credit risk.

**10.3.1.4 Valuation Allowance on a DTA Related to an AFS Debt Security**

The new guidance eliminates the diversity in practice related to the evaluation of the need for a valuation allowance for DTAs related to debt securities that are classified as AFS. Before the adoption of ASU 2016-01, entities may perform this evaluation either separately from their other DTAs or in combination with them. The new guidance clarifies that an entity should “evaluate the need for a valuation allowance on a [DTA] related to [AFS] securities in combination with the entity’s other [DTAs].”

**10.3.1.5 Changes to Disclosure Requirements**

For non-PBEs, the amendments in ASU 2016-01 eliminate the requirement to disclose the fair value of financial instruments measured at amortized cost. In addition, for such financial instruments, PBEs would not be required to disclose (1) the information related to the methods and significant assumptions used to estimate fair value or (2) a description of the changes in the methods and significant assumptions used to estimate fair value. The guidance also clarifies U.S. GAAP by eliminating the provisions in ASC 825 that had been interpreted to permit an “entry” price notion for estimating the fair value of loans for disclosure purposes. The amendments require a PBE to disclose the fair value in accordance with the exit price notion in ASC 820. In addition, all entities are required to disclose in the notes to the financial statement all financial assets and financial liabilities grouped by (1) measurement category (i.e., amortized cost or fair value — net income or OCI) and (2) form of financial asset (i.e., securities and loans/receivables).
10.3.1.6 Technical Corrections and Improvements to ASU 2016-01

In February 2018, the FASB issued ASU 2018-03 on technical corrections and improvements to ASU 2016-01 in response to feedback from stakeholders.

The amendments in ASU 2018-03 clarify certain aspects of ASU 2016-01 as follows:

- **Equity securities without readily determinable fair values** — ASU 2018-03 clarifies that an entity that measures an equity security by using the measurement alternative may change its measurement approach to a fair value method in accordance with the guidance in ASC 820 through an irrevocable election that would apply to that security and all identical or similar investments of the same issuer. Once the entity makes this election, it should measure all future purchases of identical or similar investments of the same issuer by using a fair value method in accordance with the guidance in ASC 820.

  In addition, ASU 2018-03 clarifies the guidance in ASC 321-10-55-9 (added by ASU 2016-01), which states that when applying the measurement alternative to securities without a readily determinable fair value, an entity should make adjustments from observable transactions to reflect the current fair value of the security. Specifically, ASU 2018-03 clarifies that the adjustments should be made to reflect the fair value of the security as of the date on which the observable transaction took place rather than as of the current reporting date.

- **Forward contracts and purchased options** — ASU 2018-03 clarifies that a change in observable price or impairment of underlying securities for forward contracts and purchased options on equity securities for which the measurement alternative is expected to be applied should result in the remeasurement of the entire fair value of the forward contracts and purchased options when observable transactions occur on the underlying equity securities.

- **Presentation requirements for certain fair value option liabilities** — ASU 2018-03 clarifies that when the fair value option is elected for a financial liability, the guidance in ASC 825-10-45-5 (added by ASU 2016-01) related to the disclosure of instrument-specific risk (see Section 10.3.1.3) should be applied, regardless of whether the fair value option is elected under ASC 815-15 or under ASC 825-10.

- **Fair value option liabilities denominated in a foreign currency** — ASU 2018-03 clarifies that when an entity elects to use the fair value option to measure a financial liability denominated in a currency other than the entity’s functional currency, the entity should (1) first measure the change in fair value of the liability that results from changes in instrument-specific credit risk in the currency of denomination when that change is presented separately from the total change in fair value of the financial liability and (2) then remeasure into its functional currency both components of the change in fair value of the liability by using end-of-period spot rates.

- **Transition guidance for equity securities without a readily determinable fair value** — ASU 2016-01 states that the amendments related to equity securities without readily determinable fair values should be applied prospectively. ASU 2018-03 clarifies that the prospective approach in ASU 2016-01 should be applied only to equity securities without readily determinable fair values for which the measurement alternative has been elected.
For PBEs, the amendments in ASU 2018-03 are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years beginning after June 15, 2018. PBEs with fiscal years beginning between December 15, 2017, and June 15, 2018, are not required to adopt ASU 2018-03 until the interim period beginning after June 15, 2018. PBEs with fiscal years beginning between June 15, 2018, and December 15, 2018, are not required to adopt ASU 2018-03 before adopting ASU 2016-01. For all other entities, the effective date of ASU 2018-03 is the same as the effective date of ASU 2016-01. All entities may early adopt ASU 2018-03 for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, as long as they have adopted ASU 2016-01.

In addition, in November 2018, the FASB issued a proposed ASU of Codification improvements related to ASUs 2016-01, 2016-13, and 2017-12. The comment period ended on January 18, 2019.

10.3.2 Impairment (ASU 2016-13)

10.3.2.1 Background

In June 2016, the FASB issued ASU 2016-13, which amends guidance on the impairment of financial instruments. The ASU adds to U.S. GAAP an impairment model (known as the current expected credit loss (CECL) model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes as its estimate of expected credit losses an allowance, which is presented as either (1) an offset to the amortized cost basis of the related asset (for on-balance-sheet exposures) or (2) a separate liability (for off-balance-sheet exposures). That is, the expected credit losses estimated over the lifetime of a financial instrument are recognized at inception (i.e., on day 1).

Key provisions of ASU 2016-13 are discussed below. For additional information, see Deloitte's June 17, 2016, Heads Up.

10.3.2.2 The CECL Model

10.3.2.2.1 Scope

The CECL model applies to most15 debt instruments (other than those measured at fair value), trade receivables, net investments in leases, reinsurance receivables that result from insurance transactions, financial guarantee contracts,16 and loan commitments. However, AFS debt securities are excluded from the model's scope and will continue to be assessed for impairment under the guidance in ASC 320 (the FASB moved the impairment model for AFS debt securities from ASC 320 to ASC 326-30 and has made limited amendments to the impairment model for AFS debt securities, as discussed below in Section 10.3.2.3).

10.3.2.2.2 Recognition of Expected Credit Losses

Unlike the incurred loss models in existing U.S. GAAP, the CECL model does not specify a threshold for the recognition of an impairment allowance. Rather, an entity will recognize its estimate of expected credit losses for financial assets as of the end of the reporting period. Credit impairment will be recognized as an allowance — or contra-asset — rather than as a direct write-down of the amortized cost basis of a financial asset. However, the carrying amount of a financial asset that is deemed uncollectible will be written off in a manner consistent with existing U.S. GAAP.

15 The following debt instruments would not be accounted for under the CECL model:
- Loans made to participants by defined contribution employee benefit plans.
- Policy loan receivables of an insurance entity.
- Pledge receivables (promises to give) of an NFP.
- Loans and receivables between entities under common control.

16 The CECL model does not apply to financial guarantee contracts that are accounted for as insurance or measured at fair value through net income.
10.3.2.2.3 Measurement of Expected Credit Losses

ASU 2016-13 describes the impairment allowance as a “valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset.” An entity can use a number of measurement approaches to determine the impairment allowance. Some approaches project future principal and interest cash flows (i.e., a discounted cash flow method) while others project only future principal losses. Regardless of the measurement method used, an entity’s estimate of expected credit losses should reflect those losses occurring over the contractual life of the financial asset.

When determining the contractual life of a financial asset, an entity is required to consider expected prepayments either as a separate input in the determination or as an amount embedded in the credit loss experience that it uses to estimate expected credit losses. The entity is not allowed to consider expected extensions of the contractual life unless it reasonably expects to execute a troubled debt restructuring with the borrower by the reporting date.

An entity must consider all available relevant information when estimating expected credit losses, including details about past events, current conditions, and reasonable and supportable forecasts and their implications for expected credit losses. That is, while the entity is able to use historical charge-off rates as a starting point for determining expected credit losses, it has to evaluate how conditions that existed during the historical charge-off period may differ from its current expectations and accordingly revise its estimate of expected credit losses. However, the entity is not required to forecast conditions over the contractual life of the asset. Rather, for the period beyond which the entity can make reasonable and supportable forecasts, the entity reverts to historical credit loss experience.

10.3.2.2.4 Unit of Account

The CECL model does not prescribe a unit of account (e.g., an individual asset or a group of financial assets) in the measurement of expected credit losses. However, an entity is required to evaluate financial assets within the scope of the model on a collective (i.e., pool) basis when assets share similar risk characteristics. If a financial asset’s risk characteristics are not similar to the risk characteristics of any of the entity’s other financial assets, the entity would evaluate the financial asset individually. If the financial asset is individually evaluated for expected credit losses, the entity would not be allowed to ignore available external information such as credit ratings and other credit loss statistics.

10.3.2.2.5 Write-Offs

Like current guidance, ASU 2016-13 requires an entity to write off the carrying amount of a financial asset when the asset is deemed uncollectible. However, unlike current requirements, the ASU’s write-off guidance also applies to AFS debt securities.
10.3.2.2.6 Application of the CECL Model to Trade Receivables

The CECL model applies to trade receivables that result from revenue transactions within the scope of ASC 605 (or ASC 606, if adopted). The example below, which is reproduced from ASU 2016-13 and codified in ASC 326-20-55-38 through 55-40 (Example 5), illustrates how an entity would apply the guidance to trade receivables by using a provision matrix.\(^\text{17}\)

Entity E manufactures and sells products to a broad range of customers, primarily retail stores. Customers typically are provided with payment terms of 90 days with a 2 percent discount if payments are received within 60 days. Entity E has tracked historical loss information for its trade receivables and compiled the following historical credit loss percentages:

a. 0.3 percent for receivables that are current
b. 8 percent for receivables that are 1–30 days past due
c. 26 percent for receivables that are 31–60 days past due
d. 58 percent for receivables that are 61–90 days past due
e. 82 percent for receivables that are more than 90 days past due.

Entity E believes that this historical loss information is a reasonable base on which to determine expected credit losses for trade receivables held at the reporting date because the composition of the trade receivables at the reporting date is consistent with that used in developing the historical credit-loss percentages (that is, the similar risk characteristics of its customers and its lending practices have not changed significantly over time). However, Entity E has determined that the current and reasonable and supportable forecasted economic conditions have improved as compared with the economic conditions included in the historical information. Specifically, Entity E has observed that unemployment has decreased as of the current reporting date, and Entity E expects there will be an additional decrease in unemployment over the next year. To adjust the historical loss rates to reflect the effects of those differences in current conditions and forecasted changes, Entity E estimates the loss rate to decrease by approximately 10 percent in each age bucket. Entity E developed this estimate based on its knowledge of past experience for which there were similar improvements in the economy.

At the reporting date, Entity E develops the following aging schedule to estimate expected credit losses...
Connecting the Dots

The example above from ASU 2016-13 highlights that an entity's application of the CECL model to trade receivables through the use of a provision matrix may not differ significantly from the entity's current methods for determining the allowance for doubtful accounts. However, the example illustrates that when an entity uses a provision matrix to estimate credit losses on trade receivables, it would be required to do the following when moving to an expected loss model:

- Under the CECL model, the entity would be required to consider whether expected credit losses should be recognized for trade receivables that are considered “current” (i.e., not past due). In the example above, a historical loss rate of 0.3 percent is applied to the trade receivables that are classified as current. This may be a change from current practice for many life sciences companies.

- When using historical loss rates in a provision matrix, the entity would be required to consider whether and, if so, how the historical loss rates differ from what is currently expected over the life of the trade receivables (on the basis of current conditions and reasonable and supportable forecasts about the future).

10.3.2.3 AFS Debt Securities

The CECL model does not apply to AFS debt securities. Instead, the FASB decided to make targeted improvements to the existing other-than-temporary impairment model in ASC 320 for certain AFS debt securities to eliminate the concept of “other than temporary” from that model. Accordingly, ASU 2016-13 states that an entity:

- Must use an allowance approach (vs. permanently writing down the security's cost basis).
- Must limit the allowance to the amount at which the security's fair value is less than its amortized cost basis.
- May not consider the length of time fair value has been less than amortized cost.
- May not consider recoveries in fair value after the balance sheet date when assessing whether a credit loss exists.

10.3.2.4 Disclosures

Many of the disclosures required under ASU 2016-13 are similar to those already required under U.S. GAAP as a result of ASU 2010-20. Accordingly, entities must also disclose information about:

- Credit quality.
- Allowances for expected credit losses.
- Policies for determining write-offs.
- Past-due status.
- Nonaccrual status.
- Purchased financial assets with credit deterioration (“PCD assets”).
- Collateral-dependent financial assets.

18 The amendments do not apply to an AFS debt security that an entity intends to sell or will more likely than not be required to sell before the recovery of its amortized cost basis. If an entity intends to sell or will more likely than not be required to sell a security before recovery of its amortized cost basis, the entity would write down the debt security's amortized cost to the debt security's fair value as required under existing U.S. GAAP.

19 Short-term trade receivables resulting from revenue transactions within the scope of ASC 605 and ASC 606 are excluded from these disclosure requirements.
In addition, other disclosures are required as follows:

- PBEs that meet the U.S. GAAP definition of an SEC filer\(^{20}\) must disclose credit quality indicators disaggregated by year of origination for a five-year period.

- PBEs that do not meet the U.S. GAAP definition of an SEC filer must disclose credit quality indicators disaggregated by year of origination. However, upon adoption of ASU 2016-13, they would be required to disclose such information for only the previous three years and would add another year of information each year after adoption until they have provided disclosures for the previous five years.

- Other entities are not required to disclose credit quality indicators disaggregated by year of origination.

**10.3.2.5 Effective Date and Transition**

**10.3.2.5.1 Effective Date**

For PBEs that meet the U.S. GAAP definition of an SEC filer, ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods therein.

For PBEs that do not meet the U.S. GAAP definition of an SEC filer, ASU 2016-13 is effective for fiscal years beginning after December 15, 2020, including interim periods therein.

For all other entities, ASU 2016-13 is effective for fiscal years beginning after December 15, 2021, including interim periods therein.

In addition, entities are permitted to early adopt the new guidance for fiscal years beginning after December 15, 2018, including interim periods therein.

**10.3.2.5.2 Transition Approach**

For most debt instruments, entities must record a cumulative-effect adjustment to the statement of financial position as of the beginning of the first reporting period in which the guidance is effective (modified retrospective approach). However, instrument-specific transition provisions are provided for other-than-temporarily impaired debt securities, PCD assets, and certain beneficial interests within the scope of ASC 325-40.

**10.3.2.5.3 Transition Resource Group**

In late 2015, the FASB established a credit losses TRG. Like the TRG established to discuss the new revenue recognition standard, the credit losses TRG does not issue guidance but provides feedback to the FASB on potential implementation issues. By analyzing and discussing such issues, the credit losses TRG helps the FASB determine whether it needs to take further action (e.g., by providing clarification or issuing additional guidance). For information about the topics discussed at the TRG’s meetings on June 12, 2017, June 11, 2018, and November 1, 2018, see Deloitte’s June 2017, June 2018, and November 2018 TRG Snapshot newsletters, respectively.

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\(^{20}\) Under U.S. GAAP, an SEC filer is defined as “[a]n entity that is required to file or furnish its financial statements with either of the following:
  a. The Securities and Exchange Commission (SEC)
  b. With respect to an entity subject to Section 12(i) of the Securities Exchange Act of 1934, as amended, the appropriate agency under that Section.

Financial statements for other entities that are not otherwise SEC filers whose financial statements are included in submission by another SEC filer are not included within this definition.”
Further, in November 2018, the FASB issued a proposed ASU of Codification improvements related to ASUs 2016-01, ASU 2016-13, and ASU 2017-12. The comment period ended on January 18, 2019. The improvements related to ASU 2016-13 are mostly the result of TRG issues.

In addition, in February 2019, the FASB issued a proposed ASU that would allow entities to irrevocably elect, upon adoption of ASU 2016-13, the fair value option for financial instruments that were previously recorded at amortized cost (except for held-to-maturity debt securities) and that are within the scope of ASC 326-20, provided that the instruments are eligible for the fair value option under ASC 825-10. This election would be made on an instrument by instrument basis. The proposed ASU would prevent inconsistencies resulting from the measurement of certain assets at fair value while certain other assets continue to be measured at amortized cost. Comments on the proposed ASU are due by March 8, 2019. For further information on the proposed ASU, see Deloitte’s February 11, 2019, Heads Up.

10.3.3 Hedging (ASU 2017-12)

10.3.3.1 Background

In August 2017, the FASB issued ASU 2017-12, which amends the hedge accounting recognition and presentation requirements in ASC 815. The Board’s objectives in issuing the ASU were to (1) improve the transparency and understandability of information conveyed to financial statement users about an entity’s risk management activities by better aligning the entity’s financial reporting for hedging relationships with those risk management activities and (2) reduce the complexity, and simplify the application, of hedge accounting by preparers.

For PBEs, ASU 2017-12 is effective for fiscal years beginning after December 15, 2018, and interim periods therein. For all other entities, the ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020.

Entities are permitted to early adopt the new guidance in any interim or annual period after issuance of ASU 2017-12. An entity that early adopts the updated guidance in an interim period should record any transition adjustments as of the beginning of the fiscal year that includes that interim period. Further, entities should review existing hedge accounting documentation to determine whether revisions are needed on the basis of the new standard. For any revisions required for documentation related to active hedges, entities should maintain an audit trail to show that the changes were made to conform with the new standard given that no other alterations would be allowable under U.S. GAAP (i.e., this should not be seen as an opportunity for entities to simply go back and revise existing hedge documentation).

See Deloitte’s August 30, 2017, Heads Up for additional information about ASU 2017-12.
10.3.3.2 Key Changes to the Hedge Accounting Model

ASU 2017-12 makes a number of improvements to the hedge accounting model, including those outlined below.

10.3.3.2.1 Elimination of the Concept of Separately Recognizing Periodic Hedge Ineffectiveness

ASU 2017-12 eliminates the concept of separately recognizing periodic hedge ineffectiveness for cash flow and net investment hedges (however, under the mechanics of fair value hedging, economic ineffectiveness will still be reflected in current earnings for those hedges). The Board believes that requiring an entity to record the impact of both the effective and ineffective components of a hedging relationship in the same financial reporting period and in the same income statement line item will make that entity's risk management activities and their effect on the financial statements more transparent to financial statement users.

Under this rationale, even a portion of the change in a hedging instrument's fair value that is excluded from a hedging relationship's effectiveness assessment is considered part of the hedging relationship and should be recognized in the same income statement line item as the earnings effect of the hedged item (other than amounts excluded from the assessment of effectiveness of net investment hedges). However, in a departure from the proposed ASU that formed the basis for the guidance in ASU 2017-12, the Board determined that presentation should not be prescribed for “missed forecasts” in cash flow hedges. Thus, an entity that ultimately determines that it is probable that a hedged forecasted transaction will not occur will not be required to record the amounts reclassified out of AOCI for that hedging relationship into earnings in the same income statement line item that would have been affected by the forecasted transaction.

10.3.3.2.1.1 Components Excluded From the Hedge Effectiveness Assessment

ASU 2017-12 continues to allow an entity to exclude the time value of options, or portions thereof, and forward points from the assessment of hedge effectiveness. The ASU also permits an entity to exclude the portion of the change in the fair value of a currency swap attributable to a cross-currency basis spread from the assessment of hedge effectiveness.

For excluded components in fair value, cash flow, and net investment hedges, the base recognition model under ASU 2017-12 is an amortization approach. An entity still may elect to record changes in the fair value of the excluded component currently in earnings; however, such an election will need to be applied consistently to similar hedges. The entity should disclose the method it elects.

Under the amortization approach of ASU 2017-12, an entity recognizes the initial value of the component that was excluded from the assessment of hedge effectiveness as an adjustment to earnings over the life of the hedging instrument by using a “systematic and rational method.” In each accounting period, the entity recognizes in OCI (or, for net investment hedges, the cumulative translation adjustment (CTA) portion of OCI) any difference between (1) the change in fair value of the excluded component and (2) the amount recognized in earnings under that systematic and rational method.

Note that it is possible that changes in the fair value of the hedging instrument may be presented in more than one income statement line item if the changes in the value of the hedged item affect more than one income statement line item.
### 10.3.3.2.1.2 Changes in the Fair Value of the Hedging Instrument and the Hedged Item

The following table summarizes the recognition and presentation requirements for the hedging instrument and the related hedged item under the updated hedge accounting and presentation model in ASU 2017-12:

<table>
<thead>
<tr>
<th>Component of Hedging Instrument Included in the Assessment of Hedge Effectiveness</th>
<th>Component of Hedging Instrument Excluded From the Assessment of Hedge Effectiveness</th>
<th>Hedged Item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Where Fair Value Changes Are Initially Recorded</strong></td>
<td><strong>When Hedged Item Affects Earnings</strong></td>
<td><strong>Systematic and Rational Amortization Method</strong></td>
</tr>
<tr>
<td>Fair value hedge</td>
<td>Income statement</td>
<td>N/A</td>
</tr>
<tr>
<td>Recognition</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presentation</td>
<td>Same income statement line item as the earnings effect of the hedged item</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Component of Hedging Instrument Included in the Assessment of Hedge Effectiveness</td>
<td>Component of Hedging Instrument Excluded From the Assessment of Hedge Effectiveness</td>
<td>Hedged Item</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Where Fair Value Changes Are Initially Recorded</td>
<td>When Hedged Item Affects Earnings</td>
<td>Systematic and Rational Amortization Method</td>
</tr>
<tr>
<td><strong>Cash flow hedge</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recognition</td>
<td>OCI</td>
<td>Income statement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amortization of initial value — income statement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Record in OCI any difference between the change in fair value of the excluded component and amounts recognized in earnings under the systematic and rational method</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presentation</td>
<td>OCI/AOCI (balance sheet)</td>
<td>Same income statement line item as the earnings effect of the hedged item (income statement presentation not prescribed for missed forecasts)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Same income statement line item as the earnings effect of the hedged item</td>
</tr>
</tbody>
</table>
### Table Continued

<table>
<thead>
<tr>
<th>Component of Hedging Instrument Included in the Assessment of Hedge Effectiveness</th>
<th>Component of Hedging Instrument Excluded From the Assessment of Hedge Effectiveness</th>
<th>Hedged Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where Fair Value Changes Are Initially Recorded</td>
<td>When Hedged Item Affects Earnings</td>
<td>Systematic and Rational Amortization Method</td>
</tr>
<tr>
<td><strong>Net investment hedge</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Recognition**

- **OCI (CTA)**
  - Income statement
  - Amortization of initial value — income statement
  - Record in OCI (CTA) any difference between the change in fair value of the excluded component and amounts recognized in earnings under the systematic and rational method
- **Presentation**
  - OCI/AOCI (CTA)
  - Income statement presentation not prescribed

**Presentation**

- **OCI/AOCI (CTA)**
  - Same income statement line item as the earnings effect of the hedged item (e.g., gain or loss on sale of investment)
  - Income statement presentation not prescribed

| When the hedged net investment affects earnings (i.e., upon a sale or liquidation), amounts will be reclassified out of the CTA and be presented in the same income statement line item in which the earnings effect of the net investment is presented (e.g., gain or loss on sale of investment) |

### 10.3.3.2.2 Hedge Effectiveness Assessments and Documentation Requirements — Quantitative Versus Qualitative Assessments of Hedge Effectiveness

ASU 2017-12 requires an entity to perform an initial prospective quantitative hedge effectiveness assessment (by using either a dollar-offset test or a statistical method such as regression) unless the hedging relationship qualifies for application of one of the expedients that permits an assumption of perfect hedge effectiveness (e.g., the shortcut method or critical-terms-match method). An entity may complete this initial prospective assessment after hedge designation, generally until the first quarterly hedge effectiveness assessment date, by using information available at hedge inception.
Further, if (1) an entity’s initial prospective quantitative hedge effectiveness assessment of a hedging relationship demonstrates that there is a highly effective offset and (2) the entity can, at hedge inception, “reasonably support an expectation of high effectiveness on a qualitative basis in subsequent periods,” the entity may elect to perform subsequent retrospective and prospective effectiveness assessments qualitatively. To do so, in the hedge documentation it prepares at hedge inception, the entity must (1) specify how it will perform the qualitative assessments and (2) document the alternative quantitative assessment method that it would use if it later concludes, on the basis of a change in the hedging relationship’s facts and circumstances, that subsequent quantitative assessments will be necessary. The entity may make this election on a hedge-by-hedge basis and may revise existing documentation for active hedges that use one of these expedients to include the alternative quantitative assessment method.

After an entity makes its initial election to perform qualitative assessments, it must “verify and document whenever financial statements or earnings are reported and at least every three months that the facts and circumstances related to the hedging relationship” continue to support the entity’s ability to make qualitative assessments. If the entity determines that there no longer is a sufficient basis to support continued qualitative assessments, it must subsequently assess effectiveness quantitatively by using the method that it specified in the initial hedge documentation. In future reporting periods, the entity could return to making qualitative assessments if it can support them on the basis of the same factors it had used in its original qualitative assessments.

10.3.3.2.3 Shortcut Method and Critical-Terms-Match Method

ASU 2017-12 retains both the shortcut method and critical-terms-match method and provides additional relief for entities applying those methods. Under the ASU, an entity that determines that a hedging relationship no longer meets the shortcut criteria can subsequently account for the hedging relationship by using a long-haul method (and avoid having to redesignate the original hedging relationship) if the entity can show both of the following:

a. [It] documented at hedge inception . . . which quantitative method it would use to assess hedge effectiveness and measure hedge results if the shortcut method was not or no longer is appropriate during the life of the hedging relationship.

b. The hedging relationship was highly effective on a prospective and retrospective basis in achieving offsetting changes in fair value or cash flows attributable to the hedged risk for the periods in which the shortcut method criteria were not met.

If criterion (a) is not satisfied, the hedging relationship would be invalid in the period in which the shortcut-method criteria were not satisfied and all subsequent periods; otherwise (if criterion (a) is met), the hedging relationship would be invalid in all periods in which criterion (b) was not satisfied.

In addition, ASU 2017-12 updates certain shortcut-method criteria to allow partial-term fair value hedges of interest rate risk to qualify for the shortcut method.

ASU 2017-12 also expands an entity’s ability to apply the critical-terms-match method to cash flow hedges of groups of forecasted transactions. If all other critical-terms-match criteria are satisfied, such hedges will qualify for the critical-terms-match method “if those forecasted transactions occur and the derivative matures within the same 31-day period or fiscal month.” Although entities have historically used this 31-day buffer period when applying critical-terms-match criteria, the new standard formally codifies this window, providing relief for entities that had been performing periodic analysis to demonstrate that any resulting ineffectiveness in the hedging relationship was de minimis.
10.3.3.2.4 Hedges of Interest Rate Risk

ASU 2017-12 eliminates the benchmark interest rate concept for variable-rate financial instruments but retains it for fixed-rate financial instruments. For recognized variable-rate financial instruments and forecasted issuances or purchases of variable-rate financial instruments, the ASU defines interest rate risk as “the risk of changes in the hedged item’s cash flows attributable to changes in the contractually specified interest rate in the agreement.” Thus, for example, in a hedge of the interest rate risk associated with variable debt indexed to a specified prime rate index, an entity could hedge the variability in cash flows attributable to changes in the contractually specified prime rate index. Fair value hedges of interest rate risk would continue to hedge the changes in fair value associated with changes in a specified benchmark interest rate. The ASU also adds the SIFMA Municipal Swap Rate to the list of permissible U.S. benchmark interest rates.

10.3.3.2.5 Other Targeted Improvements to Fair Value Hedges of Interest Rate Risk

ASU 2017-12 makes a number of improvements that simplify the accounting for fair value hedges of interest rate risk and make that accounting better reflect an entity’s risk management activities.

10.3.3.2.5.1 Measuring Changes in the Hedged Item’s Fair Value by Using Benchmark Component Cash Flows

Under current guidance, an entity is required to use the total contractual coupon cash flows to determine the change in fair value of the hedged item attributable to changes in the benchmark interest rate. However, ASU 2017-12 allows an entity to calculate the change in fair value of the hedged item in a fair value hedge of interest rate risk by using either (1) the full contractual coupon cash flows or (2) the cash flows associated with the benchmark interest rate component determined at hedge inception. An entity’s ability to use only the benchmark component cash flows for measurement allows the entity to reduce the net earnings effect of its hedge accounting by eliminating recognition of any economic ineffectiveness related to credit spreads.

10.3.3.2.5.2 Measuring the Fair Value of a Prepayable Instrument

For prepayable instruments such as callable debt, ASU 2017-12 states that an entity “may consider only how changes in the benchmark interest rate affect the decision to settle the hedged item before its scheduled maturity” when it calculates the change in the fair value of the hedged item attributable to interest rate risk. That is, when adjusting the carrying amount of the hedged item, an entity would consider the same factors that it considered when assessing hedge effectiveness. Before the ASU, practice had evolved to require an entity to consider all factors that might lead an obligor to settle the hedged item before its scheduled maturity (e.g., changes in interest rates, credit spreads, or other factors) even if the entity had designated only interest rate risk as the risk being hedged. The ASU allows an entity to ignore factors other than changes in the benchmark interest rate that could affect the settlement decision when it assesses hedge effectiveness and makes it easier for the hedging relationship to meet the “highly effective” threshold.

For example, when an entity that has adopted ASU 2017-12 (1) assesses hedge effectiveness in a fair value hedge of interest rate risk of callable debt and (2) measures the change in the fair value of callable debt attributable to changes in the benchmark interest rate, it can consider only how changes in the benchmark interest rate (and not changes in credit risk or other factors) would affect the obligor’s decision to call the debt.
10.3.3.2.5.3  **Partial-Term Hedges of Interest Rate Risk**

ASU 2017-12 also provides relief to entities that wish to enter into fair value hedges of interest rate risk for only a portion of the term of the hedged financial instrument. Under current guidance, successful hedging of such partial-term exposures is typically unachievable because it is difficult to find a hedging derivative that would be highly effective at offsetting changes in the fair value of the hedged exposure as a result of the difference in timing between the hedged item's principal repayment and the maturity date of the hedging derivative.

Under ASU 2017-12, an entity may measure the change in the fair value of the hedged item attributable to changes in the benchmark interest rate by “using an assumed term that begins when the first hedged cash flow begins to accrue and ends when the last hedged cash flow is due and payable.” Also, the hedged item’s assumed maturity will be the date on which the last hedged cash flow is due and payable; therefore, a principal payment will be assumed to occur at the end of the specified partial term.

10.3.3.2.6  **Ability to Designate Components of Nonfinancial Assets as Hedged Items**

Under current guidance, when an entity desires to cash flow hedge a risk exposure associated with a nonfinancial asset, it can designate as the hedged risk only the risk of changes in cash flows attributable to (1) all changes in the purchase or sales price or (2) changes in foreign exchange rates. Alternatively, for cash flow hedges of financial instruments, an entity can designate as the hedged risk either the risk of overall changes in cash flows or one or more discrete risks.

ASU 2017-12 enables an entity to designate the “risk of variability in cash flows attributable to changes in a contractually specified component” as the hedged risk in a hedge of a forecasted purchase or sale of a nonfinancial asset. The ASU defines a contractually specified component as an “index or price explicitly referenced in an agreement to purchase or sell a nonfinancial asset other than an index or price calculated or measured solely by reference to an entity's own operations.” The Board believes that enabling an entity to component hedge purchases or sales of nonfinancial assets better reflects its risk management activities in its financial reporting and will allow the entity to more easily hedge cash flow variability associated with commodities received from multiple suppliers or delivered to multiple locations. The ASU also creates greater symmetry in the hedging models for financial and nonfinancial items by allowing an entity to hedge components of the total change in cash flows for both types of items.

**Connecting the Dots**

The Board declined to provide additional guidance in ASU 2017-12 on the nature and form of contracts that could contain a contractually specified component. However, ASC 815-20-55-26A states that the “definition of a contractually specified component is considered to be met if the component is explicitly referenced in agreements that support the price at which a nonfinancial asset will be purchased or sold.”
An entity’s determination of whether it may designate as the hedged risk the variability in cash flows attributable to changes in a contractually specified component for the purchase or sale of a nonfinancial asset depends on the nature of the contract, as follows:

- If the contract is a derivative in its entirety and the entity applies the normal purchases and normal sales scope exception, the entity may designate any contractually specified component in the contract as the hedged risk (failure to apply the normal purchases and normal sales scope exception precludes designation of any contractually specified component).

- If the contract is not a derivative in its entirety, the entity may designate any remaining contractually specified component in the host contract (i.e., after bifurcation of any embedded derivatives) as the hedged risk.

In addition, ASU 2017-12 permits an entity to designate a hedge of a contractually specified component (1) for a period that extends beyond the contractual term or (2) when a contract does not yet exist to sell or purchase the nonfinancial asset if the criteria specified (see bullet points in the paragraph above) will be met in a future contract and all the other cash flow hedging requirements are met. When the entity executes the contract, it will reassess the criteria specified above to determine whether the contractually specified component continues to qualify for designation as the hedged risk. If, at the time the contract is executed, there is a change in the contractually specified component (e.g., the hedge documentation specified a commodity grade different from that in the executed contract), the entity will not be required to automatically dedesignate the hedging relationship; however, the entity must demonstrate that the hedging relationship continues to be highly effective at achieving offsetting cash flows attributable to the revised hedged risk to justify continuation of hedge accounting.

Connecting the Dots

The amendments in ASU 2017-12 do not limit this guidance on changes in the designated hedged risk to hedges of nonfinancial items. Therefore, for example, an entity also would be permitted to continue applying hedge accounting to a cash flow hedge of a financial item if (1) the designated hedged risk changes during the life of the hedging relationship (e.g., if the interest rate index referenced in the final transaction differs from that specified in the hedge documentation for the forecasted transaction) and (2) the entity can conclude that the hedging instrument is still highly effective at achieving offsetting cash flows attributable to the revised hedged risk.

10.3.3.2.7 Disclosure Requirements

ASU 2017-12 updates certain illustrative disclosure examples in ASC 815. Also, to align the disclosure requirements with the updates to the hedge accounting model, the ASU removes the requirement for entities to disclose amounts of hedge ineffectiveness. Further, the ASU requires entities to provide tabular disclosures about:

- Both (1) the total amounts reported in the statement of financial performance for each income and expense line item that is affected by fair value or cash flow hedging and (2) the effects of hedging on those line items.

- The carrying amounts and cumulative basis adjustments of items designated and qualifying as hedged items in fair value hedges. As part of such disclosures, an entity also must provide details about hedging relationships designated under the last-of-layer method, including (1) the closed portfolio’s (beneficial interest’s) amortized cost basis, (2) the designated last-of-layer amounts, and (3) the related basis adjustment for the last of layer.
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These disclosures are required for every annual and interim reporting period for which a statement of financial position and statement of financial performance are presented.

**Connecting the Dots**

Entities should exercise caution in removing specific references to ineffective or effective portions of gains and losses. Total gains and losses related to hedging activity are still required for disclosure and should be retained. For example, we believe that it would be acceptable for an entity to change “the effective portion of gains or losses” to simply “gains and losses” when issuing disclosures such as income statement geography for foreign exchange contracts designated as cash flow hedges.

### 10.3.3.3 Transition

Entities will adopt the guidance in ASU 2017-12 by applying a modified retrospective approach to existing hedging relationships\(^\text{22}\) as of the adoption date. Under this approach, entities with cash flow or net investment hedges will make (1) a cumulative-effect adjustment to AOCI so that the adjusted amount represents the cumulative change in the hedging instruments’ fair value since hedge inception (less any amounts that should have been recognized in earnings under the new accounting model) and (2) a corresponding adjustment to opening retained earnings as of the most recent period presented on the date of adoption.

In all interim periods and fiscal years ending after the date of adoption, entities should prospectively (1) present the entire change in the fair value of a hedging instrument in the same income statement line item(s) as the earnings effect of the hedged item when that hedged item affects earnings (other than amounts excluded from the assessment of net investment hedge effectiveness, for which ASU 2017-12 does not prescribe presentation) and (2) provide the amended disclosures required by the new guidance.

In addition, ASU 2017-12 allows entities to make certain one-time transition elections. See Deloitte's August 30, 2017, *Heads Up* for a detailed discussion of the one-time transition elections provided by ASU 2017-12 and the deadlines for making such elections.

**Connecting the Dots**

An entity that is considering early adoption of ASU 2017-12 should ensure that it has appropriate financial reporting internal controls in place so that it can comply with the ASU’s accounting and disclosure requirements. The entity also should give appropriate advance consideration to determining which transition elections it wishes to make since those elections must be made within a specified time after adoption. Also, ASC 815's general requirement for an entity to assess effectiveness for similar hedges in a similar manner, including the identification of excluded components, will apply to hedging relationships entered into after adoption; therefore, it will be important for the entity to determine its desired future methods for assessing the effectiveness of its hedging relationships when it adopts the ASU.

In connection with recording transition adjustments, it is important for the entity to consider the potential effects of the following:

- Deferred taxes.
- The assessment of the current hedge accounting management tool/system to ensure compliance with the new standard.

\(^{22}\) This refers to hedging relationships in which “the hedging instrument has not expired, been sold, terminated, or exercised” and that have not been dedesignated by the entity as of the date of adoption.
• Changes to the existing chart of accounts (e.g., the addition of new accounts to track amortization of excluded components or the elimination of previously used ineffectiveness accounts).

• Changes to accounting policies, operating procedures, and internal controls.

10.3.3.4 Ongoing Discussions

Industry groups, accounting firms, standard setters, and regulators are engaged in ongoing discussions of issues related to the implementation of ASU 2017-12, including (1) application of qualitative effectiveness assessments, (2) application of the last-of-layer method (e.g., accounting for basis adjustments and identification of financial instruments that are considered prepayable), (3) identification of contractually specified components of nonfinancial assets, and (4) accounting for a cash flow hedge of a forecasted transaction when the hedged risk changes. We will continue to monitor the progress of these discussions and provide updates as appropriate.

In addition, in November 2018, the FASB issued a proposed ASU of Codification improvements related to ASUs 2016-01, 2016-13, and 2017-12. The comment period ended on January 18, 2019.

10.3.4 Fair Value Measurement Disclosures (ASU 2018-13)

10.3.4.1 Background

In August 2018, the FASB issued ASU 2018-13, which changes the fair value measurement disclosure requirements of ASC 820. The amendments in this ASU are the result of a broader disclosure project called FASB Concepts Statement No. 8, Conceptual Framework for Financial Reporting — Chapter 8: Notes to Financial Statements, which the Board finalized in August 2018. The Board used the guidance in the Concepts Statement to improve the effectiveness of ASC 820’s disclosure requirements.

The table below summarizes the amendments to the fair value measurement disclosure requirements of ASC 820 that will take effect upon adoption of ASU 2018-13.

<table>
<thead>
<tr>
<th>Summary of Changes to ASC 820</th>
<th>Applicable to:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Other-Than-Nonpublic Entities</td>
</tr>
<tr>
<td>Changes in unrealized gains or losses included in other OCI for recurring Level 3 fair value measurements held at the end of the reporting period</td>
<td>Yes</td>
</tr>
<tr>
<td>Explicit requirement to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements</td>
<td>Yes</td>
</tr>
</tbody>
</table>

^{23} Nonpublic entities are still subject to the quantitative requirements in ASC 820-10-50-2(bbb)(2)(i) but are not subject to the requirements in ASC 820-10-50-2(bbb)(2)(ii).
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**Summary of Changes to ASC 820**

<table>
<thead>
<tr>
<th>Applicable to:</th>
<th>Other-Than-Nonpublic Entities</th>
<th>Nonpublic Entities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eliminated Disclosure Requirements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of and reasons for transfers between Level 1 and Level 2</td>
<td>Yes</td>
<td>No²⁴</td>
</tr>
<tr>
<td>Valuation processes for Level 3 fair value measurements</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Policy for timing of transfers between levels of the fair value hierarchy</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Changes in unrealized gains and losses included in earnings for recurring Level 3 fair value measurements held at the end of the reporting period</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Modified Disclosure Requirements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deletion of “at a minimum” from the phrase “an entity shall disclose at a minimum” to promote the appropriate exercise of discretion by entities</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ability to disclose transfers into and out of Level 3 and purchases and issues of Level 3 assets and liabilities in lieu of reconciling the opening balances to the closing balances of recurring Level 3 fair value measurements</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Clarification that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date</td>
<td>Yes</td>
<td>No²⁵</td>
</tr>
<tr>
<td>For investments in certain entities that calculate net asset value, a requirement to disclose the timing of liquidation of an investee's assets and the date when restrictions from redemption might lapse only if the investee has communicated the timing to the entity or announced the timing publicly</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**10.3.4.2 Effective Date and Transition**

ASU 2018-13 is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted upon issuance of this ASU, including in any interim period for which financial statements have not yet been issued or made available for issuance. Entities making this election are permitted to early adopt the eliminated or modified disclosure requirements²⁶ and delay the adoption of all the new disclosure requirements²⁷ until their effective date.

The ASU requires application of the prospective method of transition (for only the most recent interim or annual period presented in the initial fiscal year of adoption) to the new disclosure requirements for (1) changes in unrealized gains and losses included in OCI and (2) the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The ASU also requires prospective application to any modifications to disclosures made because of the change to

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²⁴ Under current U.S. GAAP, nonpublic entities are exempt from this disclosure requirement. Accordingly, elimination or modification of this disclosure requirement by the ASU does not affect nonpublic entities.

²⁵ See footnote 24.

²⁶ See ASC 820-10-65-12(c), which states that "an entity is permitted to early adopt the removed or modified disclosures in paragraph 820-10-50-2(bb), (c)(3), (f), and (g), paragraph 820-10-50-2G, and paragraph 820-10-50-6A(b) and (e)."

²⁷ See ASC 820-10-65-12(c), which states that an entity may "adopt the additional disclosures in paragraph 820-10-50-2(bbb)(2)(i) and (d) upon their effective date."
the requirements for the narrative description of measurement uncertainty. The effects of all other amendments made by the ASU must be applied retrospectively to all periods presented.28


10.4 On the Horizon — Proposed ASU on Classification of Debt in a Classified Balance Sheet

10.4.1 Background

In January 2017, the FASB issued a proposed ASU that would simplify the classification of debt as either current or noncurrent on the balance sheet. The guidance currently in ASC 470-10 consists of an assortment of fact-specific rules and exceptions, the application of which varies depending on the terms and conditions of the debt arrangement, management’s expectations of when debt may be settled or refinanced, and certain post-balance-sheet events. The objective of the proposed ASU is to reduce the cost and complexity of applying this guidance while maintaining or improving the usefulness of the information provided to financial statement users.

For more information about the proposed ASU, see Deloitte's January 12, 2017, Heads Up.

10.4.2 Principles-Based Approach

The proposed ASU would replace the current, fact-specific guidance with a unified principle for determining whether the classification of a debt arrangement in a classified balance sheet is current or noncurrent. An entity would classify a debt arrangement as noncurrent if either of the following criteria is met as of the financial reporting date:

- The “liability is contractually due to be settled more than one year (or operating cycle, if longer) after the balance sheet date.”
- The “entity has a contractual right to defer settlement of the liability for at least one year (or operating cycle, if longer) after the balance sheet date.”

As an exception to this classification principle, debt that is due to be settled within one year as a result of a covenant violation as of the balance sheet date would be classified as noncurrent if the debtor receives a waiver that meets certain conditions after the balance sheet date (see Section 10.4.6).

10.4.3 Scope

The proposed ASU would clarify that the balance sheet classification guidance in ASC 470-10 applies not only to nonconvertible debt arrangements but also to convertible debt within the scope of ASC 470-20 and to mandatorily redeemable financial instruments that are classified as liabilities under ASC 480-10.

10.4.4 Short-Term Obligations Expected to Be Refinanced on a Long-Term Basis

Under current U.S. GAAP, an entity that has the intent and ability to refinance a short-term obligation on a long-term basis after the financial reporting date — as indicated by the post-balance-sheet-date issuance of a long-term obligation, equity securities, or a qualifying refinancing agreement — is required to present the obligation as a noncurrent liability as of the financial reporting date. Under the proposed

28 See ASC 820-10-65-12(b), which states that “[a]n entity shall apply the pending content that links to this paragraph retrospectively to all periods presented, except for the changes in unrealized gains and losses required by paragraph 820-10-50-2(d), the range and weighted-average disclosure required by paragraph 820-10-50-2(bb)(2)(ii), and the narrative description of measurement uncertainty in accordance with paragraph 820-10-50-2(g) that are required to be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption.”
ASU, however, the entity would be required to classify the short-term obligation in current liabilities because the refinancing of debt after the financial reporting date would be viewed as a new transaction that should not be retroactively reflected on the balance sheet as of that date.

### 10.4.5 Subjective Acceleration Clauses and Debt Covenants

Under existing U.S. GAAP, the classification of long-term obligations depends in part on whether they are governed by subjective acceleration clauses (SACs) for which exercise is probable (e.g., because of recurring losses or liquidity problems). Under the proposed ASU, however, SACs and covenants within long-term obligations would affect the classification of long-term obligations only when triggered or violated, in which case disclosure of the SAC or covenant would be required.

**Connecting the Dots**

Under the proposed ASU, some liabilities that are now classified as noncurrent would be classified as current, and vice versa. For example, as a result of the proposed change to the treatment of the refinancing of short-term obligations, an entity would not be allowed to consider refinancing events after the financial reporting date but before the financial statements were issued. Thus, such debt obligations would be classified as current liabilities as of the financial reporting date. Entities should consider the timing of refinancing plans and the potential effect on the classification of short-term obligations.

### 10.4.6 Covenant Violations

Under current guidance, if the creditor can demand the repayment of a long-term obligation as of the financial reporting date because of the debtor’s violation of a debt covenant, the corresponding debt obligation is classified as noncurrent if the debtor obtains a covenant waiver before the date the financial statements are issued and certain other conditions are met. While the proposed ASU would retain similar guidance, it would require an entity to classify such debt as current if, as a result of the waiver, the entity accounts for the debt as having been extinguished. Because debt extinguishment accounting treats the debt as a newly issued instrument, the original debt obligation should be classified in current liabilities as of the balance sheet date since the creditor could demand repayment as of that date.

The proposed ASU would also clarify the application of the probability assessment that is associated with the waiver exception. Entities would be required to assess whether a violation of any other covenant not covered by the waiver is probable within 12 months from the reporting date. If so, the related debt would need to be classified as current.

### 10.4.7 Presentation and Disclosure

Under the proposed ASU, debt that is classified as noncurrent in accordance with the exception for debt covenant waivers would be presented separately on the balance sheet. Further, as previously noted, the proposed ASU would require entities to disclose information about debt covenants and SACs upon violation or trigger.

### 10.4.8 Effective Date and Transition

At the FASB’s September 13, 2017, meeting, the Board decided that for PBEs, the proposed guidance would be effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. For all other entities, the proposed guidance would be effective for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. Early adoption would be permitted. At the meeting, the Board also directed the staff to draft a final ASU for vote by written ballot.
At its January 23, 2019, meeting, as stated in the FASB’s tentative Board decisions, the Board continued redeliberations of the proposed ASU. The Board “directed the staff to continue its research on a potential alternative that considers the contractual linkage between certain debt arrangements and unused long-term financing arrangements in place at the balance sheet date. That research would consider the underlying economics of and the markets for those arrangements and illustrative examples related to unused long-term financing arrangements.”
Chapter 11 — Leases

11.1 New Leases Standard (Codified in ASC 842)

11.1.1 Background

In February 2016, the FASB issued ASU 2016-02 (the “new leases standard”). The primary objective of the new standard was to address the off-balance-sheet financing concerns related to lessees’ operating leases. Accordingly, except for those leases that qualify for the short-term lease exemption under ASC 842 (i.e., certain leases with a lease term of less than 12 months), the standard’s lessee model requires lessees to adopt a right-of-use (ROU) asset approach that brings substantially all leases onto the balance sheet. Under this approach, a lessee records an ROU asset representing its right to use the underlying asset during the lease term and a corresponding lease liability in a manner similar to the current approach for capital leases.

The FASB also addressed questions such as:

- Whether an arrangement is a service or a lease.
- What amounts should be initially recorded on the lessee’s balance sheet for the arrangement.
- How to reflect the effects of leases in the statement of comprehensive income.
- How to apply the resulting accounting in a cost-effective manner.

The standard also aligns certain underlying principles of the new lessor model with those in ASC 606, the FASB’s new revenue recognition standard, particularly those related to the evaluation of how collectibility should be considered and the determination of when profit should be recognized.

11.1.2 Scope

The new leases standard applies to leases, including subleases, of all PP&E. It does not apply to leases of or for the following:

- Intangible assets.
- Exploration for or use of nonregenerative resources.
- Biological assets.
- Inventory.
- Assets under construction.
11.1.3 Definition of a Lease

The new leases standard states that a contract is or contains a lease if the contract gives a customer “the right to control the use of identified property, plant, or equipment (an identified asset) for a period of time in exchange for consideration.” Control is considered to exist if the customer has both of the following:

- The “right to obtain substantially all of the economic benefits from use of [an identified] asset.”
- The “right to direct the use of that asset.”

An entity is required at inception to identify whether a contract is or contains a lease. The entity will reassess whether the contract is or contains a lease only in the event of a modification to the terms and conditions of the contract.

The table below summarizes key concepts related to the definition of a lease.

<table>
<thead>
<tr>
<th>Concept</th>
<th>Requirement</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of an identified asset</td>
<td>An asset is typically considered to be an identified asset if it is explicitly specified in a contract or implicitly specified at the time the asset is made available for use by the customer. However, if the supplier has substantive rights to substitute the asset throughout the period of use and would benefit economically from substituting that asset, the asset is not considered “identified,” and there is no lease for accounting purposes (see below).</td>
<td>This requirement is similar to the guidance in ASC 840-10-15 (formerly EITF Issue 01-8). An entity does not need to be able to identify the particular asset (e.g., by serial number) but must instead determine whether an identified asset is needed to fulfill the contract. Distinguishing between a lease and a capacity contract requires significant judgment. The standard clarifies that a capacity portion of an asset is an identified asset if it is physically distinct (e.g., a specific floor of a building). On the other hand, a capacity portion of a larger asset that is not physically distinct (e.g., a percentage of a pipeline) is not an identified asset unless that portion represents substantially all of the asset’s capacity.</td>
</tr>
</tbody>
</table>
| Substantive substitution rights | A supplier’s right to substitute an asset is substantive only if both of the following conditions exist:  
  - The supplier has the practical ability to substitute alternative assets throughout the period of use.  
  - The supplier would benefit economically from the exercise of its right to substitute the asset. | The FASB established this requirement because it reasoned that if a supplier has a substantive right to substitute the asset throughout the period of use, the supplier — not the customer — controls the use of the asset. |
### Table continued

<table>
<thead>
<tr>
<th>Concept</th>
<th>Requirement</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right to obtain economic benefits from use of the identified asset</td>
<td>To control the use of an identified asset, a customer must have the right to obtain substantially all of the economic benefits from use of the asset throughout the period of use.</td>
<td>The economic benefits from use of an asset include the primary output and by-products of the asset as well as other economic benefits from using the asset that could be realized from a commercial transaction with a third party.</td>
</tr>
</tbody>
</table>
| Right to direct the use of the identified asset | A customer has the right to direct the use of an identified asset throughout the period of use if either of the following conditions exists:  
  - The customer has the right to direct “how and for what purpose” the asset is used throughout the period of use.  
  - The relevant decisions about how and for what purpose the asset is used are predetermined and (1) the customer has the right to operate (or direct others to operate) the asset throughout the period of use and the supplier does not have the right to change the operating instructions or (2) the customer designed the asset in a way that predetermines how and for what purpose the asset will be used. | The relevant rights to be considered are those that affect the economic benefits derived from the use of the asset. Customers’ rights to direct the use of the identified asset include the rights to change:  
  - The type of output produced by the asset.  
  - When the output is produced.  
  - Where the output is produced.  
  On the other hand, rights that are limited to maintaining or operating the asset do not grant a right to direct how and for what purpose the asset is used. |

### 11.1.4 Embedded Leases

Often, the assessment of whether a contract is or contains a lease will be straightforward. However, the evaluation will be more complicated when an arrangement involves both a service component and a leasing component or when both the customer and the supplier make decisions about the use of the underlying asset. An asset typically is identified by being explicitly specified in a contract. However, an asset also can be identified by being implicitly specified at the time the asset is made available for the customer’s use.

**Connecting the Dots**

As discussed further in Chapter 16 of Deloitte’s *A Roadmap to Applying the New Leasing Standard*, entities in transition to ASC 842 may elect a package of transition relief (commonly referred to as “the package of three”) that, among other things, permits entities to retain historical assessments of whether contracts are or contain a lease. This means that on the effective date of the standard, for those contracts existing as of the date of adoption, the initial ASC 842 accounting is based on those contracts that meet the definition of a lease under ASC 840. Therefore, if entities elect the transition relief package, they should evaluate embedded leases that may not have been identified under legacy U.S. GAAP in accordance with ASC 840. If entities do not elect the transition relief package, they should evaluate whether contracts are or contain leases under ASC 842.
The following flowchart illustrates how to evaluate whether an arrangement is or contains a lease:
Example 11-1

**Contract Manufacturing Arrangement**

Entity A, a pharmaceutical company, enters into an arrangement with a contract manufacturer, Entity B, to purchase a particular type, quality, and quantity of active pharmaceutical ingredient (API) needed to manufacture drug compound X. Entity B has only one factory that can meet the requirements of the contract with A, and B is prohibited from supplying A through another factory or third-party suppliers. Entity A has not contracted for substantially all of B's factory's capacity.

The required quantities of API are established in the contract at inception. Entity B makes all of the decisions about the factory's operations, including when to run the factory to satisfy the required quantities and which customer orders to fulfill.

The contract does not contain a lease. The factory is an identified asset because it is implicit that B can fulfill the contract only through the use of the specific factory. However, A does not have the “right to obtain substantially all of the economic benefits from use of [an identified] asset” since the amount of capacity A has contracted for does not represent substantially all of the factory's capacity. In addition, A does not have the “right to direct the use of that asset.” While A may specify quantities of product, B has the right to direct the factory's use because it can determine when to run the factory and which customer contracts to fulfill. As a result, A does not meet the new leases standard's criterion of directing "how and for what purpose" the factory is being used, and the arrangement is not a lease.

Q&A 11-1 Determining Whether a Service Arrangement Contains a Lease

**Question**

Does an entity need to evaluate a service arrangement that involves the use of PP&E to determine whether the arrangement contains a lease?

**Answer**

Yes. In accordance with ASC 842-10-15-2, an entity is required at contract inception to identify whether a contract contains a lease. Not all contracts that contain accounting leases will be labeled as such, and accounting leases may be embedded in larger service arrangements.

Failure to identify accounting leases, including those embedded in service arrangements, could lead to a financial statement error. On the other hand, if a customer concludes that a contract is a service arrangement and that contract does not contain an embedded lease, the customer is not required to reflect the contract on its balance sheet (unless required to do so by other U.S. GAAP). The outcome of the accounting assessment of the contract may be more material to the financial statements under ASC 842 than under current U.S. GAAP since under ASC 840, the impact of operating leases on the financial statements is often the same as that of service arrangements.
Connecting the Dots

Historically, the accounting for operating leases under ASC 840 has generally not been materially different from the accounting for service contracts. However, under ASC 842, since most leases will be recognized on the balance sheet, the financial statement implications of not identifying a lease in a service contract could be more significant than under ASC 840.

For example, under ASC 840, “placed equipment” by a medical device entity may not have represented an identified asset if it was demonstrated that substitution rights existed, which could result in a conclusion that the placed equipment did not represent a lease. Under ASC 842, however, for a medical device entity to conclude that it has a substantive substitution right, it would have to demonstrate not only that it has the practical ability to substitute the placed equipment but also that it would benefit economically from the exercise of its right to substitute the asset. As a result, it is possible that more arrangements that allow for placed equipment will represent an identified asset under ASC 842.

Example 11-2

Placement of Medical Device With Sale of Consumables

Entity C is a medical device manufacturer that supplies diagnostic kits to customers. The kits can be used only on instruments manufactured by C. Entity C provides its customers with the right to use its instruments at no separate cost to the customer in exchange for a multiyear agreement to purchase annual minimum quantities of diagnostic kits. The term of the agreement generally corresponds with the expected useful life of the instruments. Entity C retains title to the instruments and is permitted to substitute them under the terms of the contract, although historically these instruments have been substituted only when they malfunction given that C does not benefit economically from the exercise of its right to substitute the asset.

The multiyear agreement to purchase diagnostic kits contains an embedded lease for the instrument system. The instrument system is an identified asset because it is implicit that C can fulfill the contract only through the customers’ use of the specific instruments. Although C has the right to substitute the instruments, the substitution right is not substantive because of the lack of economic benefit from doing so. In addition, customers have the right to control the instruments’ use because they have the right to obtain substantially all of the economic benefits from the use of the instruments during the multiyear term of the contract, which corresponds to the useful life of the instruments. Further, customers can make decisions about how and when the instruments are used when the customers perform diagnostic testing procedures.

11.2 Components of a Contract

A contract can contain both lease and nonlease components. Generally, the nonlease components are services that the supplier is also performing for the customer. For example, in a single contract, the supplier could be leasing a lab facility and related laboratory equipment to a biotechnology customer while also agreeing to provide ongoing maintenance services for the equipment throughout the period of use. Contracts may contain multiple lease components (e.g., leases of land, buildings, and equipment).
Chapter 11 — Leases

The graphic below outlines steps related to considering how to separate, and allocate consideration to, components in a contract under ASC 842.

Once an entity determines that a contract is, or contains, a lease (i.e., part or all of the contract is a lease), the entity (i.e., both the customer and the supplier) must assess whether the contract contains multiple lease components (i.e., when a contract conveys the rights to use multiple underlying assets). ASC 842-10-15-28(a) and (b) prescribe criteria for identifying whether one lease component is considered separate from other lease components in the contract.

However, land is considered an exception to the guidance in ASC 842-10-15-28. ASC 842-10-15-29 requires that a right to use land be separated from the rights to use other underlying assets (e.g., from the right to use a building that sits on top of the land), unless the effect of separating the land is insignificant to the resulting lease accounting.

Connecting the Dots

The new leases standard indicates that it is important for an entity to identify the appropriate unit of account when applying the lessee or lessor accounting models since the unit of account can affect the allocation of consideration to the components in the contract. Paragraph BC145 of ASU 2016-02 states, in part:

By way of example, regarding allocation, the Board noted that the standalone price (observable or estimated) for a bundled offering (for example, the lease of a data center) may be substantially different from the sum of the standalone prices for separate leases of the items within a bundled offering (for example, the lease of each asset in the data center). Given the substantially different accounting for lease and nonlease components in Topic 842, the allocation of contract consideration carries additional importance as compared with previous GAAP. Consequently, the Board concluded that including separate lease components guidance in Topic 842 will result in more accurate accounting that also is more consistent among entities.

The decision tree on the following page illustrates how an entity might think about identifying lease and nonlease components for each contract containing a lease.
The contract is, or contains, a lease.

Does the contract convey multiple rights of use (i.e., the rights to use multiple assets)?

---

Does the contract convey a right to use land along with the other assets?

---

Would the effect of accounting for the right to use land as a separate lease component be insignificant?

---

Does the contract convey multiple rights of use (i.e., the rights to use multiple assets)?

---

Can the customer benefit from the right of use on its own or together with other readily available resources?
Once the separate lease components are identified, entities must determine whether there are any nonlease components to be separated. An allocation of contract consideration is required for both lease and nonlease components, since they transfer a good or service to the customer. However, allocation of contract consideration does not extend to activities that do not transfer a good or service to the customer (e.g., administrative tasks and reimbursement or payment of the lessor’s costs).

Understanding the difference between lease components, nonlease components, and “noncomponents” (i.e., activities paid for by the customer that do not transfer a good or service to the customer) is critical. The table below outlines these three types of components in greater detail.

<table>
<thead>
<tr>
<th>Component Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lease Component</td>
<td>The right to use an underlying asset is considered a separate lease component if (1) a lessee can benefit from the use of the underlying asset either on its own or with other resources that are readily available and (2) the underlying asset is not highly dependent on or highly interrelated with other assets in the arrangement.</td>
</tr>
<tr>
<td>Nonlease Component</td>
<td>An activity that transfers a separate good or service to the customer is a nonlease component. For example, maintenance services consumed by the customer and bundled with the lease component in the contract would be a separate nonlease component because the performance of the maintenance transfers a service to the customer that is separate from the right to use the asset.</td>
</tr>
<tr>
<td>Noncomponent</td>
<td>Any activity in a contract that does not transfer a separate good or service to the lessee is neither a lease component nor a nonlease component; therefore, consideration in the contract would not be allocated to such an activity. For example, payments made by the customer for property taxes or insurance that covers the supplier’s interests would not represent a component in the contract.</td>
</tr>
</tbody>
</table>

ASC 842 affords lessees a practical expedient related to separating (and allocating consideration to) lease and nonlease components. That is, lessees may elect to account for the nonlease components in a contract as part of the single lease component to which they are related. The practical expedient is an accounting policy election that must be made by class of underlying asset (e.g., vehicles, information technology (IT) equipment — see the Connecting the Dots discussion below). Accordingly, when a lessee elects the practical expedient, any portion of consideration in the contract that would otherwise be allocated to the nonlease components will instead be accounted for as part of the related lease component for classification, recognition, and measurement purposes. In addition, any payments related to noncomponents would be accounted for as part of the related lease component (i.e., the associated payments would not be allocated between the lease and nonlease components).

In July 2018, the FASB approved amendments containing a new practical expedient under which lessors can elect not to separate lease and nonlease components (see ASU 2018-11 for details).
At this point, entities have identified their separate lease and nonlease components to which consideration in the contract will be allocated. Noncomponents have also been identified to ensure that consideration in the contract is not allocated to them. Next, entities must:

- Determine the consideration in the contract.
- Allocate the consideration in the contract to the separate lease and nonlease components.

**Connecting the Dots**

ASC 842 provides lessees with the following two practical expedients that may be elected as an accounting policy by “class of underlying asset”:

- It allows lessees not to separate lease and nonlease components.
- It allows lessees not to recognize lease liabilities and ROU assets for short-term leases (those under 12 months).

However, ASC 842 does not address what is meant by the phrase “class of underlying asset.” We have received a number of questions about this topic from various stakeholders, and two views have emerged:

- **View 1** — The class of underlying asset is determined on the basis of the physical nature and characteristics of the asset. For example, real estate, manufacturing equipment, and vehicles would all be reasonable classes of underlying assets given their differences in physical nature. Therefore, irrespective of whether there are different types of similar assets (e.g., within the real estate class, there may be retail stores, warehouses, and distribution centers), the class of underlying asset would be limited to the physical nature as described above.

- **View 2** — The class of underlying asset is determined on the basis of the risks associated with the asset. While an asset’s physical nature may be similar to that of other assets (e.g., retail stores, warehouses, and distribution centers are all real estate, as discussed above), each has a different purpose and use to the lessee and would therefore have a separate risk profile. Therefore, for example, it could be appropriate for the lessee to disaggregate real estate assets into separate asset classes by “type” of real estate — to the extent that the different types are subject to different risks — when applying the practical expedients in ASC 842-10-15-37 and ASC 842-20-25-2.

To support their position, proponents of View 2 refer to paragraph BC341 of ASU 2016-02, which states:

The Board decided that a lessor should treat assets subject to operating leases as a major class of depreciable assets, further distinguished by significant class of underlying asset. Accordingly, a lessor should provide the required property, plant, and equipment disclosures for assets subject to operating leases separately from owned assets held and used by the lessor. **In the Board’s view, leased assets often are subject to different risks than owned assets that are held and used** (for example, the decrease in the value of the underlying asset in a lease could be due to several factors that are not within the control of the lessor), and, therefore, users will benefit from lessors segregating their disclosures related to assets subject to operating leases from disclosures related to other owned property, plant, and equipment. **The Board further considered that to provide useful information to users, the lessor should disaggregate its disclosures in this regard by significant class of underlying asset subject to lease because the risk related to one class of underlying asset (for example, airplanes) may be very different from another (for example, land or buildings).** [Emphasis added]
Views on these questions are still developing. Therefore, we recommend that entities with concerns about such matters discuss them with their accounting advisers.

Irrespective of the views noted above, we do not think that it would be appropriate to determine the “class of underlying asset” on the basis of the lease contract with which it is associated. For example, we believe that it would be inappropriate to break real estate assets into different classes on the basis of whether they are related to gross leases or triple net leases. In that situation, the asset underlying the contract could be the same while the contract terms differ. We do not believe that such an approach is consistent with the intent of the guidance in ASC 842-10-15-37 or ASC 842-20-25-2.

11.3 Lease Classification — Lessee

Under ASC 842, at lease commencement, a lease is classified as a finance lease (for a lessee) or a sales-type lease (for a lessor) if any of the following criteria are met:

• “The lease transfers ownership of the underlying asset to the lessee by the end of the lease term.”
• “The lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise.”
• “The lease term is for the major part of the remaining economic life of the underlying asset.”
• “The present value of the sum of the lease payments and any residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset.”
• “The underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term.”

Finance leases are accounted for in a manner similar to how entities account for a financed purchase arrangement. The lessee recognizes interest expense and amortization of the ROU asset, which result in a greater expense in the early years of the lease than in the later years of the lease. The ROU asset related to an operating lease is amortized to expense on a straight-line basis unless another systematic and rational basis is more representative of the pattern in which benefit is expected to be derived from the right to use the underlying asset. For both types of leases, the lessee recognizes an ROU asset for its interest in the underlying asset and a corresponding lease liability.

Connecting the Dots

While many aspects of the lease classification criteria under ASC 842 are consistent with existing guidance, bright-line tests (i.e., whether the lease term is for 75 percent or more of the economic life of the asset or whether the present value of the lease payments, including any guaranteed residual value, is at least 90 percent of the fair value of the leased asset) are noticeably absent. However, ASC 842-10-55-2 states that these tests are “one reasonable approach to assessing the criteria.” On the basis of this implementation guidance, entities often can use bright-line thresholds as policy elections when evaluating the classification of a lease arrangement under the new leases standard. However, as with all policy elections, it is important for entities to consider the full range of impact and the need for policy elections to be consistently applied.
11.4 Lessor Accounting

After proposing multiple different amendments to lessor accounting, the FASB ultimately decided to make only minor modifications to the current lessor model. The most significant changes (1) align the profit recognition requirements under the lessor model with the new revenue standard and (2) amend the lease classification criteria for a lessor to make them consistent with those for a lessee. Accordingly, the new leases standard requires a lessor to use the classification criteria discussed above to classify a lease, at its commencement, as a sales-type lease, a direct financing lease, or an operating lease.

Accounting for existing leveraged leases (leases that met the criteria in ASC 840-10-25-43(c)) is grandfathered during transition. Otherwise, leveraged lease accounting is eliminated going forward from the date of adoption.

Q&A 11-2 Commencement Loss Resulting From Significant Variable Payments in a Sales-Type or Direct Financing Lease

While the FASB’s goal was to align lessor accounting with the revenue guidance in ASC 606, an important distinction between the two may affect lessors in the life sciences industry. Under ASC 606, variable payments are estimated and included in the transaction price, subject to a constraint. By contrast, under ASC 842, variable lease payments not linked to an index or rate are generally excluded from the determination of a lessor’s lease receivable. Accordingly, sales-type or direct financing leases that have a significant variable lease payment may result in recognition of a loss at commencement because the measurement of the lease receivable plus the unguaranteed residual asset is less than the net carrying value of the underlying asset.

For example, it is not uncommon for a hospital to contract with a medical device owner for the use of specific medical equipment for a major part of the economic life of the equipment. This type of arrangement is often priced in such a way that the consideration is based entirely on the hospital’s ongoing purchase of “consumables,” which allow the equipment to function as designed, and may have no minimum volume requirement. The medical device owner is willing to accept variable consideration in the arrangement because demand for the associated health care services suggests that a sufficient volume of consumables will be purchased by the hospital over the term of the contract to make the arrangement profitable.

Question

Should a lessor recognize a loss at lease commencement when its initial measurement of the net investment in a sales-type or direct financing lease is less than the carrying value of the underlying asset?

Answer

Yes. At the FASB’s November 30, 2016, meeting, the Board acknowledged that a lessor’s initial measurement of a sales-type or direct financing lease that includes a significant variable lease payment component may result in a loss at lease commencement if the lease receivable plus the unguaranteed residual asset is less than the net carrying value of the underlying asset being leased. The Board discussed whether a loss at commencement would be appropriate in these situations or whether other possible approaches would be acceptable, such as (1) incorporating variable lease payments subject to a constraint (by reference to ASC 606) or (2) using a negative discount rate to avoid the loss at commencement. The Board expressed its belief that while stakeholders may disagree with the outcome of recognizing a loss at commencement, the new leases standard is clear about how the initial measurement guidance should be applied to sales-type and direct financing leases.
11.5 Lease Modifications

A lease modification is any change to the contractual terms and conditions of a lease. Under the new leases standard, a lease modification is accounted for as follows:

- A lessee or lessor accounts for a lease modification as a separate contract (i.e., separate from the original lease) when the modification (1) grants the lessee an additional ROU asset and (2) the price of the additional ROU asset is commensurate with its stand-alone price.

- A lessee accounts for a lease modification that is not a separate contract by using the discount rate as of the modification effective date to adjust the lease liability and ROU asset for the change in the lease payments. The modification may result in a gain or loss if the modification results in a full or partial termination of an existing lease.

- A lessor accounts for a lease modification in a manner that is generally consistent with the contract modification guidance in ASC 606.

Example 11-3

**Lease Modifications**

**Scenario 1 — Modification Resulting in a Separate Contract**

Company A, a pharmaceutical entity (the lessee), enters into an arrangement to lease 15,000 square feet of office space in a complex for 20 years. At the beginning of year 10, A and the lessor agree to amend the original lease to include an additional 5,000 square feet of space adjacent to the existing space currently being leased when the current tenant vacates the property in 18 months. The increase in lease consideration as a result of the amendment is commensurate with the market rate for the additional 5,000 square feet of space in the complex. Company A would account for this modification (i.e., the lease of the additional 5,000 square feet) as a separate contract because the modification provides A with a new ROU asset at a price that reflects that asset's stand-alone price. While A would be required to disclose certain information about the lease modification, it would not be required to separately record any amounts in its statement of financial position until the separate lease's commencement date (i.e., 18 months from entering into the modification).

**Scenario 2 — Modification Not Resulting in a Separate Contract**

Company A, a pharmaceutical entity (the lessee), enters into an arrangement to lease 15,000 square feet of office space in a complex for 20 years. At the beginning of year 10, A and the lessor agree to amend the original lease by reducing the annual rental payments from $60,000 to $50,000 for the remaining 10 years of the agreement. Because the modification results in a change only to the lease consideration (i.e., the modification does not result in an additional ROU asset), A would remeasure its lease liability to reflect (1) a 10-year lease term, (2) annual lease payments of $50,000, and (3) A's incremental borrowing rate (or the rate the lessor charges the lessee if such rate is readily determinable) as of the modification effective date. Company A would recognize the difference between the new and old lease liabilities as an adjustment to the ROU asset.

11.6 Subleases

When the original lessee subleases the leased asset to an unrelated third party, the lessee becomes the intermediate lessor in the sublease arrangement. As the intermediate lessor of a leased asset, the entity would determine the classification of the sublease independently from its determination of the classification of the original lease (i.e., the head lease). Under the new leases standard, the intermediate lessor would classify the sublease on the basis of the underlying asset (i.e., it would assess the term of the sublease relative to the remaining economic life of the underlying asset). When evaluating lease classification and measuring the net investment in a sublease classified as a sales-type or direct financing lease, the original lessee (as a sublessor) should use the rate implicit in the lease if it is determinable. If the implicit rate is not determinable, the original lessee would use the discount rate that it used to determine the classification of the original lease.
In addition, offsetting is generally prohibited on the balance sheet and in the income statement unless the arrangement meets the offsetting requirements of ASC 210-20.

**Example 11-4**

**Accounting for a Sublease Under ASC 842**

As a lessee, Company A, a life sciences entity, enters into a building lease with a 30-year term. The building has a depreciable life of 40 years. At the end of year 5, A enters into an agreement with Company B, a generics and consumer health entity, under which A subleases the building to B for 20 years.

As the lessor in its agreement with B, A would account for the lease to B (the sublease) as an operating lease because (1) the term of the sublease is not for a major part of the remaining life of the underlying asset of the sublease (i.e., the sublease term of 20 years represents only 57 percent of the remaining 35-year life of the building) and (2) A has concluded that no other classification criteria would result in the transfer of control of the underlying asset.

11.7 Sale-and-Leaseback Transactions

The seller-lessee in a sale-and-leaseback transaction must evaluate the transfer of the underlying asset (sale) under the requirements of ASC 606 to determine whether the transfer qualifies as a sale (i.e., whether control has been transferred to the customer). The existence of a leaseback by itself would not preclude the transaction from qualifying as a sale (i.e., it would not indicate that control has not been transferred) unless the leaseback is classified as a finance lease. In addition, if the arrangement includes an option for the seller-lessee to repurchase the asset, the transaction would not qualify as a sale unless both of the following criteria are met:

- The option is priced at the fair value of the asset on the date of exercise (see below regarding sale-and-leaseback transactions involving real estate).
- There are alternative assets that are substantially the same as the transferred asset and readily available in the marketplace.

If the transaction does not qualify as a sale, the seller-lessee and buyer-lessor would account for the transaction as a financing arrangement (i.e., the buyer-lessor would account for its payment as a financial asset and the seller-lessee would record a financial liability).

If the transaction qualifies as a sale, the leaseback is accounted for in the same manner as all other leases (i.e., the seller-lessee and buyer-lessor would account for the leaseback under the new accounting guidance for lessees and lessors, respectively).

**Q&A 11-3 Whether a Seller-Lessee Repurchase Option in a Sale and Leaseback of Real Estate Precludes Treatment of the Transfer as a Sale**

**Question**

Would the inclusion of a seller-lessee repurchase option in a sale and leaseback of real estate preclude the transfer from qualifying as a sale under ASC 606?
**Answer**

Yes. Sale-and-leaseback transactions involving real estate that include a repurchase option will not meet the criteria of a sale under ASC 606 regardless of whether the repurchase option is priced at fair value. During the FASB’s redeliberations on ASU 2016-02, the Board noted that sale-and-leaseback transactions involving real estate that include a repurchase option would not meet the second criterion in ASC 842-40-25-3. Paragraph BC352(c) of ASU 2016-02 states, in part:

> When the Board discussed [ASC 842-40-25-3], Board members generally observed that real estate assets would not meet criterion (2). This is because real estate is, by nature, “unique” (that is, no two pieces of land occupy the same space on this planet) such that no other similar real estate asset is “substantially the same.”

Therefore, regardless of whether the repurchase option is priced at fair value, the unique nature of real estate would prevent a sale-and-leaseback transaction involving real estate that includes a repurchase option from satisfying the second criterion in ASC 842-40-25-3 since there would be no alternative asset that is substantially the same as the one being leased. Accordingly, in a manner similar to current U.S. GAAP, the new leases standard would preclude sale-and-leaseback accounting for transactions involving any repurchase options on real estate.

11.8  Effective Date and Transition

For PBEs, the new leases standard is effective for fiscal years beginning after December 15, 2018 (i.e., calendar periods beginning on January 1, 2019), including interim periods therein. For all other entities, the standard is effective for annual periods beginning after December 15, 2019 (i.e., calendar periods beginning on January 1, 2020), and interim periods beginning after December 15, 2020. Early adoption is permitted. Entities are required to use a modified retrospective transition method of adoption. The FASB also issued ASU 2018-11 so that entities may elect not to recast their comparative periods in transition (the “Comparatives Under 840 Option”). See Section 11.9.

11.8.1  Additional Implementation Considerations

Discussed below are some of the additional implementation considerations that life sciences entities should thoughtfully address while transitioning to ASC 842. For further discussion, see Deloitte’s October 17, 2018; August 7, 2018; December 5, 2017; April 25, 2017; and March 1, 2016 (updated July 12, 2016), Heads Up newsletters.

11.8.1.1  Operational Considerations

To implement the lessee accounting requirements, all individual contracts and arrangements will need to be collected, maintained, and evaluated, including information related to real estate contracts and equipment contracts (e.g., manufacturing equipment, laboratory equipment). In addition, it may be necessary to obtain information outside of contractual arrangements, including (1) the fair value of an asset, (2) the asset’s estimated useful life, (3) the incremental borrowing rate, and (4) certain judgments related to lease options. The ability to acquire this data may be particularly challenging when contract documentation is prepared in a foreign language and could vary as a result of local business practices.
11.8.1.1.1 Materiality Threshold

When implementing the lessee accounting requirements, life sciences companies are likely to consider a materiality threshold, especially for high volume, low value, leased assets (e.g., laptops). As discussed further in Q&A 2-1 of Deloitte’s *A Roadmap to Applying the New Leasing Standard*, ASC 842 does not contain a “small-ticket item” exception similar to that in IFRS 16. Although materiality is generally a consideration in the application of all accounting standards, life sciences entities should not simply default to their existing capitalization threshold for PP&E for the following reasons:

- The existing capitalization threshold for PP&E is unlikely to include the effect of the additional asset base introduced by the ASU. That is, the addition of another set of ROU assets not previously recognized on an entity’s balance sheet may require a refreshed analysis of the entity’s capitalization thresholds to ensure that the aggregated amounts will not become material.

- The existing capitalization threshold for PP&E does not take into account the liability impact to the balance sheet. Under ASC 842, if an entity wishes to establish a threshold that will be used to avoid accounting for both ROU assets and lease liabilities on the balance sheet, it must consider the materiality, in the aggregate, of all of its ROU assets and related lease liabilities that would be excluded when it adopts such a threshold.

One reasonable approach to developing a capitalization threshold for leases may be to use the lesser of the following:

- A capitalization threshold for PP&E, including ROU assets (i.e., the threshold takes into account the effect of leased assets determined in accordance with ASU 2016-02).

- A recognition threshold for liabilities that takes into account the effect of lease liabilities determined in accordance with the ASU.

Another reasonable approach to developing a capitalization threshold for leases may be to record all lease liabilities but to subject the related ROU assets to such a threshold. Under this approach, if an ROU asset is below the established capitalization threshold, it would immediately be recognized as an expense. In subsequent periods, entities would amortize the lease liability by using the effective interest method, under which a portion of the periodic lease payments would reduce the liability and the remainder would be recognized as interest expense.

11.8.1.1.2 Variable Expense

Life sciences entities will mostly likely have contracts with variable lease payments (e.g., international real estate contracts with index-based payment escalations). Entities may find it necessary to create a new general ledger account to track variable lease costs for disclosure purposes in accordance with ASC 842-20-50-4 and to consider impacts of variable lease payments on the accounts payable process.

11.8.1.2 Application of Judgment and Estimation

Entities must use judgment and make estimates under a number of the new as well as current leases requirements. Judgment is often required in the assessment of a lease’s term, which would affect whether the lease qualifies for the short-term exemption and therefore for off-balance-sheet treatment. In addition, since almost all leases will be recognized on the balance sheet, judgment in distinguishing between leases and services becomes more critical under the new guidance.
11.8.1.2.1 Discount Rates

In particular, upon transition, entities will need to recognize ROU assets and lease obligations by using an appropriate discount rate on the date of transition. Compliance with this requirement may be difficult for entities with a significant number of leases since they will need to identify the appropriate incremental borrowing rate for each lease on the basis of factors associated with the underlying lease terms (e.g., lease tenor, asset type, residual value guarantees). That is, entities would not be permitted to use the same discount rate for all of their leases unless the leased assets and related terms are similar.

Additional considerations include:

- **Secured versus unsecured rate** — The definition of the incremental borrowing rate under ASC 842 requires lessees to obtain a collateralized or secured borrowing rate. Unsecured rates are likely to be higher, which would result in a lower lease liability. If a lessee does not borrow on a secured basis, it will most likely need to make adjustments to its unsecured borrowing rates to reflect a rate of a secured borrowing.

- **Parent versus subsidiary rate** — Sometimes it may be appropriate for a subsidiary to use an incremental borrowing rate other than its own. This will depend on the nature of the lease negotiations and the resulting terms and conditions (e.g., a consolidated group with a centralized treasury function that negotiates on behalf of all of its subsidiaries to benefit from its superior credit).

- **Leases denominated in a foreign currency** — When determining an incremental borrowing rate for a lease denominated in a foreign currency, entities should use assumptions that are consistent with a rate that the entities would obtain to borrow in the same currency in which the lease is denominated. The incremental borrowing rate should still reflect a collateralized rate in the relevant foreign environment.

- **Discount rate in transition** — Entities should determine the discount rate as of the effective date of ASC 842 when initially measuring lease liabilities (assuming the entities continue to account for comparative periods under ASC 840). When selecting a discount rate, entities should elect as an accounting policy (and consistently apply to all contracts) to use either an interest rate corresponding to the original lease term or an interest rate corresponding to the remaining lease term.

- **Developing a method** — Life sciences entities should define a method for calculating the incremental borrowing rate that is auditable and supportable as of the transition date and on an ongoing basis.

11.8.1.3 Information Technology Systems

As a result of implementing the requirements of the new leases standard, life sciences entities will most likely need to enhance their existing IT systems. The extent of the enhancements will be based on the size and complexity of an entity’s lease portfolio and its existing leasing systems. As with any change to existing systems, an entity will need to consider the business ramifications (i.e., the potential impact on existing processes, systems, and controls) and the requirements of system users (e.g., the entity’s legal, tax, financial planning and analysis, real estate, treasury, and financial reporting functions). Also, management may need to consider system changes that will enable the entity to estimate, before adoption of ASU 2016-02, the ASU’s effect on key performance indicators and metrics, tax filings, debt covenants, or other filings. In addition, to the extent that an entity prepares IFRS statutory reports for foreign subsidiaries, its systems will need to distinguish between ASU 2016-02 and IFRS 16 and will need to be equipped to handle the differences between the two standards.
11.8.1.4 **Income Taxes**

A lease's classification for accounting purposes does not affect its classification for tax purposes. A life sciences entity will therefore continue to be required to determine the tax classification of a lease under the applicable tax laws. While the classification may be similar for either purpose, the differences in tax and accounting principles and guidance often result in book/tax differences. Thus, once an entity implements the new leases standard, it will need to establish a process to account for these differences. The requirement that entities reevaluate their leases under the new guidance also presents an opportunity for entities to reassess the tax treatment of such leases as well as their data collection and processes. Since the IRS considers a taxpayer's tax treatment of leases to be a method of accounting, any changes to existing methods may require IRS consent. Entities should also consider the potential state tax issues that may arise as a result of the new guidance, including how the classification of the ROU asset may affect the apportionment formula in the determination of state taxable income and how the significant increase in recorded lease assets could affect the determination of franchise tax payable.

11.8.1.5 **Covenant Considerations**

Given the requirement to bring most leases onto the balance sheet, many companies, including those in the life sciences industry, will reflect additional liabilities on their balance sheets after adopting the new leases standard. An entity's determination of whether the increased leverage will negatively affect any key metrics or potentially cause debt covenant violations is a critical aspect of its planning for the new standard's implementation. This determination may depend, in part, on how various debt agreements define and limit indebtedness as well as on whether the debt agreements use “frozen GAAP” covenants (i.e., covenants that are based on GAAP at the time the debt was issued). ASU 2016-02 requires presentation of operating lease liabilities outside traditional debt, which may provide relief. Regardless, we believe that it will be critical for all life sciences entities to determine the potential effects of ASU 2016-02 on debt covenants and begin discussions with lenders early if they believe that violations are likely to occur as a result of adopting the ASU.

11.9 **Amendments to New Leases Standard**

The FASB received comments on ASC 842 and deliberated on several issues that had been raised. As a result of these discussions, the Board issued the following ASUs that amend certain aspects of ASC 842:

- **ASU 2018-10 on improvements to ASC 842** — In July 2018, the FASB issued ASU 2018-10, which makes 16 narrow-scope amendments (i.e., minor changes and clarifications) to certain aspects of ASC 842.

- **ASU 2018-11 on targeted improvements to ASC 842** — In July 2018, the FASB issued ASU 2018-11 to provide entities with relief from the costs of implementing certain aspects of the new leases standard. Specifically, under the amendments in ASU 2018-11:
  - Entities may elect not to recast the comparative periods presented when transitioning to ASC 842.
  - Lessors may elect not to separate lease and nonlease components when certain conditions are met.

For further discussion, see Deloitte's August 7, 2018, *Heads Up.*
11.10 Land Easement Practical Expedient for Transition to ASC 842 (ASU 2018-01)

11.10.1 Background
Various stakeholders raised questions about how ASC 842 should be applied to land easements. Also known as rights of way, land easements represent the right to use, access, or cross another entity’s land for a specified purpose. In January 2018, the FASB issued ASU 2018-01, which allows an entity, as an optional transition practical expedient, not to apply ASC 842 to existing or expired land easements that it did not previously account for as leases under ASC 840.

11.10.2 Key Provisions
An entity that elects to use the practical expedient in ASU 2018-01 should evaluate under ASC 842 new or modified land easements (i.e., land easements that were entered into or modified on or after the date of adoption of ASC 842). An entity that does not elect to use this practical expedient should evaluate all existing or expired land easements under ASC 842 to determine whether they meet the new leases standard’s definition of a lease.

11.10.3 Effective Date
The amendments in ASU 2018-01 affect the amendments in ASU 2016-02. The effective date and transition requirements are the same for both ASUs. An entity that early adopted ASC 842 should apply the guidance in ASU 2018-01 as of the issuance date of that ASU.
Chapter 12 — Initial Public Offerings

12.1 Introduction
In recent years, there has been an increasing number of life sciences initial public offerings (IPOs). Nearly 40 percent of all IPOs from 2014 through mid-2018 were in the life sciences industry, as compared with only 15 percent during the preceding 10-year period.\(^1\) The majority of those life sciences IPOs were in the biotechnology subsector, with many qualifying for emerging growth company (EGC) filing status.

12.1.1 What Are EGCs?
An EGC is a category of issuer that was established in 2012 under the Jumpstart Our Business Startups Act (commonly referred to as the JOBS Act). EGCs were granted additional accommodations in 2015 under the Fixing America's Surface Transportation Act (commonly referred to as the FAST Act). The less stringent regulatory and reporting requirements for EGCs are intended to encourage such companies to undertake public offerings. A private company undertaking an IPO will generally qualify as an EGC if it (1) has total annual gross revenues of less than $1.07 billion during its most recently completed fiscal year and (2) has not issued more than $1 billion of nonconvertible debt over the past three years. Once a company completes its IPO, it must meet additional criteria to retain EGC status.

12.1.2 Accommodations Applicable to EGCs
There are many potential benefits for registrants that file an IPO as an EGC. For example, EGCs:

- Need only two years of audited financial statements in an IPO of common equity.\(^2\)
- Are not required to present selected financial data for periods before the first year of financial statements presented in the IPO.
- May omit financial information (including audited financial statements) from an IPO registration statement if that financial information is related to periods that are not reasonably expected to be required at the time the registration statement becomes effective.
- May elect not to adopt new or revised accounting standards until they become effective for private companies (i.e., nonissuers).
- Are eligible for reduced executive compensation disclosures.
- May submit a draft IPO registration statement to the SEC for confidential review.

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\(^1\) Statistics compiled from publicly available historical IPO information furnished by Nasdaq and Yahoo.

\(^2\) This accommodation is limited to an IPO of common equity. As the SEC clarifies in paragraph 10220.1 of the SEC Financial Reporting Manual (FRM), an entity will generally need to include three years of audited financial statements when entering into an IPO of debt securities or filing an Exchange Act registration statement, such as a Form 10, to register securities.
EGCs are not required to apply the above accommodations and may choose to provide some scaled disclosures but not others. However, if an EGC has elected to opt out of the extended transition period for complying with new or revised accounting standards, this election is irrevocable. Therefore, a registrant, its advisers, and the underwriters should consider which EGC accommodations to use early in the IPO process. The SEC expects EGCs to disclose, in their IPO registration statements, their EGC status and to address related topics, such as the exemptions available to them, risks related to the use of those exemptions, and how and when they may lose EGC status.

Certain scaled disclosure provisions apply to other SEC rules. For example, the accommodations listed above can typically also be applied to any other entities’ financial statements required under SEC Regulation S-X, Rules 3-05 and 3-09.

In addition, an entity that was an EGC at the time it initially submitted its IPO registration statement for SEC review but that subsequently ceased to be an EGC is allowed to continue to use EGC accommodations until the earlier of either the date it completes its IPO under that registration statement or one year after it ceased to be an EGC.

If an EGC elects to confidentially submit its IPO registration statements to the SEC, the submission will not immediately be posted on EDGAR (unlike many non-EGC registration statements, which are released on EDGAR shortly after being filed). However, the IPO registration statement must be “publicly” filed at least 15 days before the EGC’s road show. In addition, any draft registration statements and related comment letters and responses that the EGC submitted to the SEC staff for confidential review will be publicly released on EDGAR by the staff after the IPO registration statement becomes effective.

After the SEC registrant’s IPO, provided that the registrant retains its EGC status, additional accommodations are available for its ongoing reporting obligations. One of the most significant of these accommodations exempts EGCs from the requirement to obtain, from the entity’s independent registered public accounting firm, an auditor’s report on the entity’s internal control over financial reporting. EGCs are also exempt, unless the SEC deems it is necessary, from any future PCAOB rules that may require (1) rotation of independent registered public accounting firms or (2) supplements to the auditor’s report, such as communications regarding critical audit matters, which are required for certain other issuers beginning in 2019.

After going public, a registrant will retain its EGC status until the earliest of:

- The last day of the fiscal year in which its total annual gross revenues exceed $1.07 billion.
- The date on which it has issued more than $1 billion in nonconvertible debt securities during the previous three years.
- The date on which it becomes a large accelerated filer. This is an annual assessment performed on the last day of the fiscal year.
- The last day of the fiscal year after the fifth anniversary of the date of the first sale of common equity securities under an effective Securities Act registration statement for an EGC.

Topic 10 of the FRM summarizes many of the SEC staff’s views on EGC-related issues. To further assist registrants, the SEC’s Division of Corporation Finance has issued frequently asked questions on numerous aspects of the JOBS Act, many of which address matters related to qualifying for EGC status and the filing requirements for EGCs.
Section 12.2 below highlights accounting and disclosure issues commonly encountered by life sciences entities that are associated with IPOs. For more information as well as insights into topics not addressed below, see Deloitte's *A Roadmap to Initial Public Offerings* and *A Roadmap to SEC Comment Letter Considerations, Including Industry Insights*.

### 12.2 Industry Issues

#### 12.2.1 Financial Statements of Businesses Acquired or to Be Acquired (Rule 3-05)

<table>
<thead>
<tr>
<th>Example of an SEC Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>We note that you consummated the [Company A] acquisition . . . but to date you have not filed audited financial statements of the acquired business or pro forma information relating to the acquisition. Please provide us with your calculations of the significance tests outlined in Rule 1-02(w) of Regulation S-X that you used in applying the requirements of Rule 3-05 and Article 11 of Regulation S-X.</td>
</tr>
</tbody>
</table>

As discussed in Chapter 4, it is common for life sciences entities to engage in significant M&A activity. When a significant business acquisition is consummated, or it is probable that it will be consummated, the registrant may be required to file certain financial statements of the acquired business or to be acquired business (acquiree) in accordance with Rule 3-05. While existing registrants are subject to periodic reporting requirements for significant acquisitions, a company is not subject to such requirements before an IPO. Therefore, in the context of an initial registration statement, a company must evaluate all acquisitions since the beginning of the earliest financial statement period presented (see examples below). As a result, a registrant could be required to prepare and file preacquisition financial statements for an acquiree that was purchased several years before the IPO.

The following factors govern whether, and for what period, the acquiree's financial statements are required for a consummated or probable acquisition:

- **Definition of a business** — Rule 3-05 applies to an acquisition of a business. The definition of a “business” for SEC reporting purposes differs from the definition under ASC 805 for U.S. GAAP purposes and focuses primarily on the continuity of revenue-producing activities. Under SEC guidelines, the legal form of an acquisition (i.e., acquisition of assets vs. acquisition of a legal entity) has no impact on the determination of whether the acquiree is a business.

- **Significance** — The highest level of significance based on the following three tests is used to determine the financial statements, if any, that an entity is required to provide in the registration statement:
  - **Investment test** — The GAAP purchase price is compared with the total assets of the registrant on the basis of its most recent preacquisition annual financial statements.
  - **Asset test** — The acquiree's total assets are compared with the registrant's total assets on the basis of the most recent preacquisition annual financial statements of each company.

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3 Under Item 2.01 of Form 8-K, a registrant is required to file a Form 8-K to announce a significant business acquisition within four business days of consummation and to include the required financial statements within 71 calendar days.

4 SEC Regulation S-X, Rule 11-01(d), states, in part, “[T]he term business should be evaluated in light of the facts and circumstances involved and whether there is sufficient continuity of the acquired entity's operations prior to and after the transactions so that disclosure of prior financial information is material to an understanding of future operations. A presumption exists that a separate entity, a subsidiary, or a division is a business.”
Income test — The acquiree’s pretax income from continuing operations is compared with the registrant’s pretax income from continuing operations on the basis of the most recent preacquisition annual financial statements of each company.

The significance tests in SEC Regulation S-X, Rule 1-02(w), can be quite complex. For more information, see Deloitte’s *A Roadmap to SEC Reporting Considerations for Business Combinations*.

### 12.2.1.1 Periods of Financial Statements Required

The significance of an acquisition is based on the highest individual percentage generated when a registrant performs the three tests described above. The following table summarizes the acquiree financial statement requirements at various significance thresholds:

<table>
<thead>
<tr>
<th>Highest Level of Significance</th>
<th>Financial Statements Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 20 percent</td>
<td>• Acquisition is not individually significant; no financial statements are required.</td>
</tr>
<tr>
<td></td>
<td>• For acquisitions after the most recent audited balance sheet date included in the registration statement, individually insignificant acquisitions are evaluated in the aggregate.</td>
</tr>
<tr>
<td>Exceeds 20 percent but not 40 percent</td>
<td>• Audited balance sheet as of the end of the most recent fiscal year.</td>
</tr>
<tr>
<td></td>
<td>• Audited statements of operations, comprehensive income, cash flows, and changes in stockholders’ equity for the most recent fiscal year.</td>
</tr>
<tr>
<td></td>
<td>• Unaudited financial statements as of and for the appropriate interim period preceding the acquisition and the corresponding interim period in the prior year.</td>
</tr>
<tr>
<td>Exceeds 40 percent but not 50 percent</td>
<td>• Audited balance sheets as of the end of the two most recent fiscal years.</td>
</tr>
<tr>
<td></td>
<td>• Audited statements of operations, comprehensive income, cash flows, and changes in stockholders’ equity for the two most recent fiscal years.</td>
</tr>
<tr>
<td></td>
<td>• Unaudited financial statements as of and for the appropriate interim period preceding the acquisition and the corresponding interim period in the prior year.</td>
</tr>
<tr>
<td>Exceeds 50 percent</td>
<td>• Audited balance sheets as of the end of the two most recent fiscal years.</td>
</tr>
<tr>
<td></td>
<td>• Audited statements of operations, comprehensive income, cash flows, and changes in stockholders’ equity for the three most recent fiscal years.</td>
</tr>
<tr>
<td></td>
<td>• Unaudited financial statements as of and for the appropriate interim period preceding the acquisition and the corresponding interim period in the prior year.</td>
</tr>
<tr>
<td></td>
<td>• Exceptions:</td>
</tr>
<tr>
<td></td>
<td>◦ If revenues of the acquired business are less than $100 million in the most recent fiscal year, the earliest year can be omitted.</td>
</tr>
<tr>
<td></td>
<td>◦ If the acquiring company qualifies as an EGC, no more than two years of financial statements are required in an IPO for common equity or in a Form 10.</td>
</tr>
</tbody>
</table>

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5 SEC Regulation S-X, Rule 1-02(w), indicates that pretax income from continuing operations is “income from continuing operations before income taxes,” extraordinary items, and cumulative effect of a change in accounting principle “exclusive of amounts attributable to any noncontrolling interests.”

6 Separate financial statements of individually insignificant businesses acquired since a registrant’s latest audited year-end balance sheet are not required if their aggregate significance does not exceed 50 percent. If the aggregate significance exceeds 50 percent, audited financial statements for the mathematical majority of the businesses must be provided for only the most recent fiscal year. See Section 2035 of the FRM for further reporting considerations and other circumstances in which the rule may apply.

7 For consummated acquisitions, this generally results in interim financial statements as of the acquiree’s last fiscal quarter-end completed before the closing of the acquisition and for the year-to-date interim period ending on this date, along with the corresponding period in the prior fiscal year.

8 See footnote 7.

9 See footnote 7.

10 See Question 16 of the SEC’s “Jumpstart Our Business Startups Act Frequently Asked Questions,” which states, in part, “If the significance test results in a requirement to present three years of financial statements for these other entities, we would not object if the emerging growth company presents only two years of financial statements for these other entities in its registration statement.”
For more information, see Deloitte’s A Roadmap to Accounting for Business Combinations.

12.2.2 Pro Forma Disclosures
A registrant in an IPO may have consummated a transaction, or be contemplating a probable transaction, in which presentation of pro forma financial information is required. The objective of providing pro forma financial information is to enable investors to understand and evaluate the continuing impact of a transaction by showing how the transaction might have affected the historical financial position and results of operations of the registrant had it been consummated at an earlier date.

The requirements related to presentation and preparation of pro forma financial information are addressed in SEC Regulation S-X, Article 11, as well as Topic 3 of the FRM. The requirements for pro forma financial information under Article 11 are separate and distinct from the requirements to present supplementary pro forma information for a business combination under ASC 805. For more information about the pro forma information disclosures that ASC 805 requires for a completed business combination, see Section 12.2.2.5.

12.2.2.1 Circumstances in Which Presentation of Pro Forma Information Is Required
Article 11 lists several circumstances in which a registrant may need to provide pro forma financial information. As part of an IPO, corporate reorganizations, changes in capitalization, and the use of proceeds are frequently reflected in pro forma financial information; however, a registrant needs to consider whether any other significant events or transactions have occurred or are probable and, if so, whether information about those significant events or transactions would also be meaningful to investors on a pro forma basis. Factors that may affect whether a registrant needs to provide pro forma financial information in a registration statement include (1) whether the event or transaction is significant; (2) whether it is already reflected in the historical financial statements; (3) if the event has not yet occurred, whether it is probable; and (4) in the case of the acquisition of a business, whether the separate financial statements of the acquiree are included in the registration statement.

12.2.2.2 Basic Presentation Requirements
Pro forma financial information, which is unaudited, typically includes an introductory paragraph, a pro forma balance sheet, pro forma income statements, and accompanying explanatory notes. The introductory paragraph briefly describes the transaction(s), the entities involved, the periods for which the pro forma financial information is presented, and any other information that may help readers understand the content of the pro forma information. Ordinarily, the pro forma balance sheet and income statement are presented in a columnar format that shows historical financial information of the registrant (and the target in the case of a business combination), pro forma adjustments, and pro forma totals. Further, each pro forma adjustment should include a reference to explanatory notes that clearly discuss the assumptions involved and how the adjustments are derived or calculated. In the limited cases in which only a few adjustments are required and those adjustments are easily understood, a registrant may include a narrative presentation of the pro forma effects of a transaction in lieu of full pro forma financial information.
12.2.2.3 Pro Forma Periods Presented

A pro forma balance sheet is required as of the same date as the registrant's most recent balance sheet included in the IPO registration statement. In the computation of pro forma balance sheet adjustments, it is assumed that the transaction was consummated on the balance sheet date. Pro forma income statements are required for both the registrant's most recent fiscal year and any subsequent year-to-date interim period included in the IPO registration statement. In the computation of pro forma income statement adjustments, it is assumed that the transaction was consummated at the beginning of the most recently completed fiscal year. The SEC normally does not permit registrants to prepare pro forma information for more than one complete fiscal year. However, a registrant must provide pro forma information for all periods presented in its historical financial statements if the pro forma information reflects the impact of a discontinued operation or a reorganization of entities under common control. A pro forma balance sheet is not required if the transaction is already reflected in the historical balance sheet. Similarly, a pro forma income statement is not required if the transaction is included in the historical financial statements for the full period covered by the pro forma income statement. Depending on the facts and circumstances, a registrant may need to include a pro forma income statement (or statements) but would not be required to include a pro forma balance sheet.

12.2.2.4 Pro Forma Adjustments

Pro forma financial information should only give effect to events that are (1) directly attributable to the transaction; (2) factually supportable; and (3) with respect to the pro forma income statement, are expected to have a continuing impact on the registrant. Common pro forma adjustments include the allocation of purchase price related to a business acquisition on a pro forma balance sheet and the related adjustments to depreciation and amortization in the pro forma income statement, the issuance or repayment of debt and the related impact on interest expense, the effects of new contractual arrangements, and any related income tax impact. The requirement to have a continuing impact applies only to the pro forma income statement, which can cause the same item to be treated differently on the pro forma balance sheet than it is in the pro forma income statement. For example, the pro forma income statement may include a pro forma adjustment to remove direct acquisition costs reflected in the historical income statement but would not include a pro forma adjustment to record similar costs that are anticipated but have not yet been incurred. Although these costs are directly attributable to the acquisition, because they are nonrecurring, they would not be considered to have a continuing impact and therefore should not be reflected in the pro forma totals for the income statement. Conversely, on the pro forma balance sheet, any accrued direct acquisition costs in the historical balance sheet would not be reversed and a pro forma adjustment would be recorded to accrue for any additional direct acquisition costs anticipated, provided that the amount was factually supportable.

Pro forma adjustments would normally not be made to (1) reflect actions planned or taken by management after a business combination (e.g., restructuring or integration costs), (2) reverse the impact of unusual costs in the historical results (e.g., a goodwill impairment), or (3) project future synergies or cost savings. In such cases, one or both of the “directly attributable” and “factually supportable” requirements typically would not be met.

Connecting the Dots

In the context of an IPO, a common question is whether the incremental cost of being a public company should be included as a pro forma adjustment. Pro forma disclosure in an initial registration statement would typically not include the expected incremental costs of being a public company because it is unlikely that such costs would meet the criteria for being factually supportable.
12.2.2.5 ASC 805 Requirements

In addition to the pro forma financial information required for a business combination or probable business combination, an entity must disclose pro forma financial information in the notes to the financial statements in accordance with ASC 805, when a business combination is completed.

ASC 805-10-50-2(h) requires that an acquirer that meets the definition of a public entity disclose the following:

- “The amounts of revenue and earnings of the acquiree since the acquisition date included in the consolidated income statement for the reporting period.”
- The “revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period.”
- “The nature and amount of any material, nonrecurring pro forma adjustments directly attributable to the business combination(s) included in the reported pro forma revenue and earnings.”

The ASC 805 pro forma information must be disclosed (1) in the period in which a business combination occurs or (2) if a business combination is completed after the reporting date but before the financial statements were issued. Further, if multiple immaterial business combinations that are material in the aggregate occur in a reporting period, ASC 805 pro forma information should be disclosed in the aggregate for those business combinations.

The ASC 805 pro forma disclosures are required only for public entities. Therefore, an entity may not have provided these disclosures in its financial statements before becoming a public entity. However, if a material business combination or multiple immaterial business combinations that are material in the aggregate have occurred in any of the reporting periods presented in the registration statement, the entity would be required to provide these disclosures in its registration statement.

For more information about business combinations, see Chapter 4 of this publication and Deloitte’s A Roadmap to SEC Reporting Considerations for Business Combinations.

12.2.3 Predecessor Financial Information

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<thead>
<tr>
<th>Example of an SEC Comment</th>
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<tr>
<td>We note you sold 100% of your interest in [Entity A] in December 2014 in order to reduce your reliance on sales of [Product X] and focus on new business opportunities. We note your previous operations now appear insignificant in relation to the acquired operations of [Entity B]. Please tell us your consideration of whether [Entity B] is your predecessor entity for which predecessor financial statements would be required. In your response, please discuss in detail the portion of your business that remained after the sale of [Entity A] and before the acquisition of [Entity B].</td>
</tr>
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</table>
In addition to pro forma information, entities should consider whether predecessor financial information is required after a material acquisition. If a registrant has not had substantive operations for all periods presented in an IPO registration statement, it is important to consider whether the registrant has a “predecessor” company or business. Section 1170 of the FRM indicates that the designation of an acquired business as a predecessor is based on both of the following criteria:

- The registrant “succeeds to substantially all of the business (or a separately identifiable line of business) of another entity (or group of entities).”
- The “registrant's own operations before the succession appear insignificant relative to the operations assumed or acquired.”

A predecessor’s historical financial information is considered important to an investing decision. As a result, the registrant’s financial statements and those of its predecessor together should typically cover all periods required by SEC Regulation S-X, with no lapse in audited periods. Further, the predecessor financial statements must be audited in accordance with PCAOB, not AICPA, standards and will be required in both the IPO and subsequent periodic reports.

The SEC staff believes that when a newly formed company (i.e., a “newco”) is formed to acquire multiple entities in conjunction with an IPO, instances in which there is no predecessor would generally be rare, even if the newco is substantive and was deemed the accounting acquirer. The staff highlighted a number of factors for registrants to consider in determining the predecessor, including, but not limited to, (1) the order in which the entities are acquired, (2) the size of the entities, (3) the fair value of the entities, and (4) the ongoing management structure. The staff has indicated that no one item is determinative on its own and that there could also be more than one predecessor.

12.2.4 Share-Based Compensation Valuation

An entity that is preparing for an IPO may have a share-based compensation strategy designed to retain and attract employees. Share-based compensation often is in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, or an employee stock purchase plan (ESPP). In addition, an entity may use share-based compensation to purchase goods, IP, or services from third-party vendors or service providers. Management should consider the financial reporting implications associated with each of the various types of share-based compensation arrangements that an entity may enter into with employees and nonemployees.

One of the most significant inputs related to measuring share-based compensation is the underlying valuation of the entity’s shares. A pre-IPO entity should become familiar with the U.S. GAAP and SEC valuation requirements, including differences between valuation methods for public entities and those for nonpublic entities. The discussion below summarizes some of the more significant considerations related to share-based compensation for an entity contemplating an IPO.

ASC 718 identifies three ways for nonpublic entities to measure share-based compensation awards (the terms below are defined in ASC 718-20):

- By using fair value, which is the amount at which an asset (or liability) could be bought (or incurred) or sold (or settled) in a current transaction between willing parties (i.e., other than in a forced or liquidation sale).
- By using a calculated value, which is a measure of the value of a stock option or similar instrument determined by substituting the historical volatility of an appropriate industry sector index for the expected volatility of a nonpublic entity’s share price in an option-pricing model.
- By using intrinsic value, which is the amount by which the fair value of the underlying stock exceeds the exercise price of an option or similar instrument.
12.2.4.1 Fair-Value-Based Measurement

Nonpublic entities should make an effort to value their equity-classified awards by using a fair-value-based measure. A nonpublic entity may look to recent sales of its common stock directly to investors or common-stock transactions in secondary markets. However, observable market prices for a nonpublic entity’s equity shares may not exist. In such an instance, a nonpublic entity could apply many of the principles of ASC 820 to determine the fair value of its common stock, often by using either a market approach or an income approach (or both). A “top-down method” may be applied, which involves first valuing the entity, then subtracting the fair value of debt, and then using the resulting equity valuation as a basis for allocating the equity value among the entity’s equity securities. While not authoritative, the AICPA Accounting & Valuation Guide *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the “AICPA Valuation Guide”) emphasizes the importance of using contemporaneous valuations from independent valuation specialists to determine the fair value of equity securities.

12.2.4.2 Calculated Value

When stock options or similar instruments are granted by a nonpublic entity, the entity should try to use a fair-value-based measure to value those equity-classified awards. However, in certain instances, a nonpublic entity may not be able to reasonably estimate the fair-value-based measure of its options and similar instruments because it is not practicable to estimate the expected volatility of the nonpublic entity’s share price. In these cases, the nonpublic entity should substitute the historical volatility of an appropriate industry sector index for the expected volatility of its own share price. In the assessment of whether it is practicable for the entity to estimate the expected volatility of its own share price, the following factors should be considered:

- Whether there is an internal market for the shares (e.g., investors or employees can purchase and sell shares).
- Previous issuances of equity in a private transaction or convertible debt provide indications of the historical or implied volatility of the share price.
- Whether there are similarly sized public entities, including those within an index in the same industry, whose historical or implied volatilities could be used as a substitute for the nonpublic entity’s expected volatility.

If, after considering the relevant factors, the nonpublic entity determines that estimating the expected volatility of its own share price is not practicable, it should use the historical volatility of an appropriate industry sector index as a substitute in estimating the fair-value-based measure of its awards.

An appropriate industry sector index would be one that is narrow enough to reflect the nonpublic entity’s nature and size. For example, the use of the New York Stock Exchange Acra Pharmaceutical Index is not an appropriate industry sector index for a small nonpublic biotechnology development entity because it represents neither the industry in which the nonpublic entity operates nor the size of the entity. The volatility of an index of smaller biotechnology companies would be a more appropriate substitute for the expected volatility of the share price.

Under ASC 718-10-55-58, if an industry sector index is used for determining the expected volatility of a nonpublic entity’s share price, the index’s historical volatility rather than its implied volatility must be used. However, ASC 718-10-55-56 states that “in no circumstances shall a nonpublic entity use a broad-based market index like the S&P 500, Russell 3000, or Dow Jones Wilshire 5000.”
A conclusion that estimating the expected volatility of the nonpublic entity's share price is not practicable may be subject to scrutiny. If an appropriate industry sector index can be identified, there would generally be an expectation that similar entities from the selected index could be identified to estimate the expected volatility of the share price and that therefore, the fair-value-based measurement method would be the most appropriate method to use.

In measuring compensation cost related to awards, a nonpublic entity should change its measurement method from using a calculated value to using a fair-value-based measure when (1) the expected volatility of the nonpublic entity's share price can be subsequently estimated or (2) the nonpublic entity becomes a public entity. ASC 718-10-55-27 states that the valuation technique an entity selects should be used consistently and should not be changed unless a different valuation technique is expected to produce a better estimate of a fair-value-based measure (or, in this case, a change to a fair value-based measure). The guidance goes on to state that a change in valuation technique should be accounted for as a change in accounting estimate under ASC 250 and should be applied prospectively to new awards.

Therefore, for existing equity-classified awards (i.e., unvested equity awards that were granted before the switch from the calculated value method to a fair-value-based measure), compensation cost would continue to be recognized on the basis of the calculated value determined as of the grant date unless the award was subsequently modified. The fair-value-based method should be used to measure all awards granted after the change from the calculated value method to the fair-value-based method.

ASC 718-20-55-76 through 55-83 provide an example of when it may be appropriate for a nonpublic entity to use the calculated value method.

### 12.2.4.3 Intrinsic Value
Nonpublic entities can make a policy election to measure all liability-classified awards that have not yet been settled at intrinsic value (instead of at their fair-value-based measure or calculated value) as of the end of each reporting period. However, it is preferable to use the fair-value-based method to justify a change in accounting principle under ASC 250. Therefore, a nonpublic entity that has elected to measure its liability-classified awards at a fair-value-based measure (or calculated value) would not be permitted to subsequently change to the intrinsic value method other than upon adoption of ASU 2016-09. It is important to note that equity-classified awards may not be measured at intrinsic value.

ASC 718-30-55-12 through 55-20 illustrate the application of the intrinsic value method for liability-classified awards granted by a nonpublic entity.

### 12.2.4.4 Cheap Stock

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<th>Example of an SEC Comment</th>
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<tr>
<td>Please tell us the estimated IPO price range. To the extent there is a significant difference between the estimated grant-date fair value of your common stock during the past twelve months and the estimated IPO price, please discuss for us each significant factor contributing to the difference.</td>
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The SEC often focuses on “cheap stock” issues in connection with a nonpublic entity’s preparation for an IPO. The SEC staff is interested in the rationale for any difference between the reported fair value measurements of the underlying common stock of share-based payment awards and the anticipated IPO price. In addition, the staff will challenge valuations that are significantly lower than prices paid by investors to acquire similar stock. If the differences cannot be supported, there may be need to record a cheap-stock charge. Registrants should be able to reconcile the change in the estimated fair value of the underlying equity between the award grant date and the IPO by taking into account, among other things, intervening events and changes in assumptions that support the change in fair value. Since share-based payments are often a compensation tool to attract and retain employees, an unrecorded cheap-stock charge could be material and, in some cases, lead to a restatement of the financial statements.

An entity preparing for an IPO should refer to paragraph 7520.1 of the FRM, which outlines considerations registrants should take into account when the “estimated fair value of the stock is substantially below the IPO price.”

The AICPA Valuation Guide highlights differences between pre-IPO and post-IPO valuations. One significant difference is that the valuation of a nonpublic entity’s securities often includes a discount for lack of marketability. Several quantitative methods have been developed to estimate that discount. Since the discounts could be significant, the SEC staff has frequently inquired about a registrant’s pre-IPO valuations. Specifically, during the registration statement process, the staff may ask an entity to (1) reconcile recent fair values with the anticipated IPO price, (2) describe valuation methods, (3) justify significant valuation assumptions, (4) outline significant intervening events, and (5) discuss the weight given to stock sale transactions.

In addition to considerations related to cheap stock, companies commonly face issues caused by infrequently obtaining independent valuations, because the dates of those valuations do not always coincide with the grant dates for share-based payment awards. As a result, the current fair value of the underlying shares as of the grant date will need to be assessed. Management should consider qualitative and quantitative factors when assessing the current fair value of the underlying shares as of the grant date if a current independent valuation is not readily available. Further, the use of an interpolation or extrapolation framework should be considered for estimating the fair value of the underlying shares when equity is granted between two independent valuations or is granted after an independent valuation. For details on interpolation and extrapolation methods, including examples, see Deloitte’s March 17, 2017, Financial Reporting Alert.

We encourage companies planning an IPO in the foreseeable future to use the AICPA Valuation Guide and to consult with valuation specialists. Pre-IPO valuations should be supportable, and companies should be prepared to respond to questions the SEC may have during the registration statement process.

In its disclosures, a registrant undergoing an IPO typically identifies share-based compensation as a critical accounting estimate because the lack of an active market for the pre-IPO shares makes the estimation process complex and subjective.

The SEC staff had historically asked registrants to expand the disclosures in their critical accounting estimates to add information about the valuation methods and assumptions used for share-based compensation in an IPO. While Section 9520 of the FRM indicates that registrants should significantly reduce disclosures about share-based compensation and the valuation of pre-IPO common stock in the critical accounting estimates section of MD&A, paragraph 9520.2 of the FRM indicates that the SEC staff may continue to request that companies “explain the reasons for valuations that appear unusual (e.g., unusually steep increases in the fair value of the underlying shares leading up to the IPO).” Such
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requests are meant to ensure that regardless of the length of disclosures, a registrant's analysis and assessment support its accounting for share-based compensation; they do not necessarily indicate that the registrant's disclosures need to be enhanced.

At the Practising Law Institute’s “SEC Speaks in 2014” Conference, the SEC staff discussed the types of detailed disclosures it had observed in IPO registration statements that had prompted the updates to Section 9520 of the FRM. The staff noted that registrants have historically included:

- A table of equity instruments issued during the past 12 months.
- A description of the methods used to value the registrant's pre-IPO common stock (i.e., income approach or market approach).
- Detailed disclosures about certain select assumptions used in the valuation.
- Discussion of changes in the fair value of the company's pre-IPO common stock. Such discussion included each grant leading up to the IPO and resulted in repetitive disclosures.

The staff indicated that despite the volume of share-based compensation information included in IPO filings, disclosure of such information was often incomplete because registrants did not discuss all relevant assumptions related to common-stock valuations. Further, disclosures about registrants' pre-IPO common-stock valuations were often not relevant after an IPO and were generally removed from their periodic filings after the IPO. The SEC staff expressed the view that streamlined share-based compensation disclosures make reporting more meaningful and reduce the volume of information. The staff also indicated that by eliminating unnecessary information, registrants could reduce many prior disclosures “down to one paragraph.”

At the conference, the SEC staff also provided insights into how registrants would be expected to apply the guidance in paragraph 9520.1 of the FRM and thereby reduce the share-based compensation disclosures in their IPO registration statements:

- The staff does not expect much detail about the valuation method registrants used to determine the fair value of their pre-IPO shares. A registrant need only state that it used the income approach, the market approach, or a combination of both. Further, while registrants are expected to discuss the nature of the material assumptions they used, they would not be required to quantify such assumptions. For example, if a registrant used an income approach involving a discounted cash flow method, it would only need to provide a statement indicating that a discounted cash flow method was used and involved cash flow projections that were discounted at an appropriate rate. No additional details would be needed.

- Registrants would have to include a statement indicating that the estimates in their share-based compensation valuations are highly complex and subjective but would not need to provide additional details about the estimates. Registrants would also need to include a statement disclosing that such valuations and estimates will no longer be necessary once the entity goes public because it will then rely on the market price to determine the fair value of its common stock.

The staff emphasized that its ultimate concern is whether registrants correctly accounted for pre-IPO share-based compensation. Accordingly, the staff will continue to ask for supplemental information to support valuations and accounting conclusions — especially when the fair value of a company's pre-IPO common stock is significantly less than the expected IPO price.
12.2.4.5 Internal Revenue Code Section 409A

When granting share-based payment awards, a nonpublic entity should be mindful of the tax treatment of such awards and the related implications. Section 409A of the Internal Revenue Code (IRC) contains requirements related to nonqualified deferred compensation plans that can affect the taxability of holders of share-based payment arrangements. If a nonqualified deferred compensation plan (e.g., one issued in the form of share-based payments) fails to comply with certain IRC rules, the tax implications and penalties at the federal level (and potentially the state level) can be significant for holders.

Under U.S. tax law, stock option awards can generally be categorized into two groups:

- Statutory options, including incentive stock options (ISOs) and ESPPs that are qualified under IRC Sections 422 and 423, respectively. The exercise of an ISO or a qualified ESPP does not result in a tax deduction for the grantor unless the employee or former employee makes a disqualifying disposition.

- Nonstatutory options (also known as “NQSOs” or “NSOs”). The exercise of an NQSO results in a tax deduction for the grantor that is equal to the intrinsic value of the option when exercised.

The ISOs and ESPPs described in IRC Sections 422 and 423, respectively, are specifically exempt from the requirements of IRC Section 409A. Other NQSOs are outside the scope of Section 409A if certain requirements are met. One significant requirement is that the exercise price must not be below the fair market value of the underlying stock as of the grant date. Accordingly, it is imperative to establish a supportable fair market value of the stock to avoid unintended tax consequences. While Section 409A also applies to public entities, the valuation of share-based grants for such companies is subject to less scrutiny because the market prices of their shares are generally observable. Companies should consider consulting with their tax advisers about any tax implications of their nonqualified deferred compensation plans. Among other details, companies should ensure that they understand (1) which of their compensation plans and awards are subject to the provisions of Section 409A and (2) how to ensure that those plans and awards remain compliant with Section 409A so that the consequences of noncompliance are avoided.

12.2.4.6 Transition From Nonpublic-Entity to Public-Entity Status

The measurement alternatives available to a nonpublic entity (calculated value and intrinsic value) are no longer appropriate after an IPO. In addition, the practical expedient related to determining the expected term of certain options and similar instruments is different for public and nonpublic entities. To estimate the expected term as a midpoint between the requisite service period and the contractual term of an award, entities will need to comply with the requirements of the SEC’s simplified method.

In SAB Topic 14.B, the SEC discusses various transition issues associated with valuing share-based payment awards related to an entity’s becoming public (e.g., when the entity files its initial registration statement with the SEC), including the following:

- If a nonpublic entity historically measured equity-classified share-based payment awards at their calculated value, the entity should continue to use that approach for share-based payment awards granted before the date it becomes a public entity unless those awards are subsequently modified, repurchased, or canceled.

- If a nonpublic entity historically measured liability-classified share-based compensation awards on the basis of their intrinsic value and the awards are still outstanding, the measurement of those liability awards should be fair value based when the entity becomes a public entity.
• Upon becoming a public entity, the entity is prohibited from retrospectively applying the fair-value-based measurement to its awards if it used calculated value or intrinsic value before the date it became a public entity.

• Upon becoming a public entity, the entity should clearly describe in its MD&A the change in accounting policy that ASC 718 will require in subsequent periods and any reasonably likely material future effects of the change.

The SEC's guidance does not address how an entity should account for a change from the intrinsic value method for measuring liability-classified awards to the fair-value-based method. In informal discussions, the SEC staff indicated that it would be acceptable to record the effect of such a change as compensation cost in the current period or to record it as the cumulative effect of a change in accounting principle in accordance with ASC 250. While the preferred approach is to treat the effect of the change as a change in accounting principle under ASC 250, with the cumulative effect of the change recorded accordingly, recording it as compensation cost is not objectionable given the SEC's position. Under either approach, entities' financial statements should include the appropriate disclosures.

ASC 250-10-45-5 states that an “entity shall report a change in accounting principle through retrospective application of the new accounting principle to all prior periods, unless it is impracticable to do so.” Retrospective application of the effects of a change from intrinsic value to fair value would be impracticable because objectively determining the assumptions an entity would have used for the prior periods would be difficult without the use of hindsight. Therefore, the change would be recorded as a cumulative-effect adjustment to retained earnings and applied prospectively, as discussed in ASC 250-10-45-6 and 45-7. This conclusion is consistent with the guidance in SAB Topic 14.B that states that entities changing from nonpublic to public status are not permitted to apply the fair-value-based method retrospectively.

12.2.4.7 Valuation Assumptions — Expected Term

Example of an SEC Comment

Please more fully explain to us why you believe it is appropriate to use the simplified method to estimate the expected life of your stock options. Please also tell us when you expect sufficient historical information to be available to you to determine expected life assumptions and address the impact that your current approach has had on your financial statements. Refer to SAB Topic 14.D.2.

ASC 718-10-55-30 states, in part:

The expected term of an employee share option or similar instrument is the period of time for which the instrument is expected to be outstanding (that is, the period of time from the service inception date to the date of expected exercise or other expected settlement).
Although ASC 718 does not specify a required method for estimating the expected term of an award, such a method must be objectively supportable. Similarly, historical observations should be accompanied by information about why future observations are not expected to change, and any adjustments to these observations should be supported by objective data. ASC 718-10-55-31 identifies the following factors an entity may consider in estimating the expected term of an award:

- **The vesting period of the award** — Options generally cannot be exercised before vesting; thus, an option’s expected term cannot be less than its vesting period.

- **Employees’ historical exercise and postvesting employment termination behavior for similar grants** — Historical experience should be an entity’s starting point for determining expectations of future employee exercise and postvesting termination behavior. Historical exercise patterns should be modified when current information suggests that future behavior will differ from past behavior.

  For example, rapid increases in an entity’s stock price after the release of a new product in the past could have caused more employees to exercise their options as soon as the options vested. If a similar increase in the entity’s stock price is not expected, the entity should consider whether it is appropriate to adjust the historical exercise patterns.

- **Expected volatility of the underlying share price** — An increase in the volatility of the underlying share price tends to result in an increase in exercise activity because more employees take advantage of increases in an entity’s share price to realize potential gains on the exercise of the option and subsequent sale of the underlying shares. ASC 718-10-55-31(c) states, “An entity also might consider whether the evolution of the share price affects an employee’s exercise behavior (for example, an employee may be more likely to exercise a share option shortly after it becomes in-the-money if the option had been out-of-the-money for a long period of time).” The exercise behavior based on the evolution of an entity’s share price can be more easily incorporated into a lattice model than into a closed-form model.

- **Blackout periods** — A blackout period is a period during which exercise of an option is contractually or legally prohibited. Blackout periods and other arrangements that affect the exercise behavior associated with options can be included in a lattice model. Unlike a closed-form model, a lattice model can be used to calculate the expected term of an option by taking into account restrictions on exercises and other post vesting exercise behavior.

- **Employees’ ages, lengths of service, and home jurisdictions** — Historical exercise information could have been affected by the profile of the employee group. For example, during a bull market, some entities are more likely to have greater turnover of employees since more opportunities are available. Many such employees will exercise their options as early as possible. These historical exercise patterns should be adjusted if similar turnover rates are not expected to recur in the future.

If historical exercise and post vesting employment termination behavior are not readily available or do not provide a reasonable basis on which to estimate the expected term, alternative sources of information may be used. For example, a lattice model may be used to estimate the expected term. The expected term is not an input in the lattice model but is inferred on the basis of the output of the lattice model. In addition, other relevant and supportable information, such as industry averages or published academic research, should be considered. When external peer group information is taken into account, there should be evidence that such information has been sourced from entities with comparable facts and circumstances. Further, practical expedients may be used to estimate the expected term for certain awards. Question 5 of SEC SAB Topic 14.D.2 notes that if a public entity concludes that “its historical share option exercise experience does not provide a reasonable basis upon which to estimate expected term,” the entity may use what the SEC staff describes as a “simplified method” to develop the expected-
term estimate. Under the simplified method, the public entity uses an average of the vesting term and the original contractual term of an award. The method applies only to awards that qualify as “plain-vanilla” options.

As the SEC states in SAB Topic 14.D.2, the simplified method applies only to awards that qualify as plain-vanilla options. A share-based payment award must possess all of the following characteristics to qualify as a plain-vanilla option:

- “The share options are granted at-the-money.”
- “Exercisability is conditional only on performing service through the vesting date” (i.e., the requisite service period equals the vesting period).
- “If an employee terminates service prior to vesting, the employee would forfeit the share options.”
- “If an employee terminates service after vesting, the employee would have a limited time to exercise the share options (typically 30–90 days).”
- “The share options are nontransferable and nonhedgeable.”

If an award has a performance or market condition, it would not be considered a plain-vanilla option. Entities should evaluate all awards to determine whether they qualify as plain-vanilla options.

The SEC staff believes that public entities should stop using the simplified method for stock option grants if more detailed external information about exercise behavior becomes available. In addition, the staff frequently comments on the use of the simplified method and, in certain instances, asks registrants to explain why they believe that they were unable to reasonably estimate the expected term on the basis of their historical stock option exercise information.

In accordance with the SEC’s guidance in Question 6 of SAB Topic 14.D.2, a registrant that uses the simplified method should disclose in the notes to its financial statements (1) that the simplified method was used, (2) the reason the method was used, (3) the types of stock option grants for which the simplified method was used if it was not used for all stock option grants, and (4) the period(s) for which the simplified method was used if it was not used in all periods presented.

### 12.2.4.8 Valuation Assumptions — Expected Volatility

**Example of an SEC Comment**

We note that the expected volatility of your Class A common stock is based on a peer group in the industry in which the Company does business. Please tell us what consideration you gave to using the Company's historical pricing data in arriving at a volatility assumption. In addition, tell us what consideration you gave to disclosing the reason for the continued reliance on a peer group in the industry in arriving at this assumption. We refer you to ASC 718-10-55-37 and SAB Topic 14.D.1.

ASC 718-10-55-36 states, in part:

Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. Option-pricing models require expected volatility as an assumption because an option's value is dependent on potential share returns over the option's term. The higher the volatility, the more the returns on the shares can be expected to vary — up or down.
ASC 718 does not require entities to use a single method for estimating the expected volatility of the underlying share price; rather, ASC 718-10-55-35 states that the objective of estimating such volatility is “to determine the assumption about expected volatility that marketplace participants would be likely to use in determining an exchange price for an option.” ASC 718-10-55-37 lists factors that entities would consider in estimating the expected volatility of the underlying share price. The method selected to perform the estimation should be applied consistently from period to period, and entities should adjust the factors or assign more weight to an individual factor only on the basis of objective information that supports such adjustments. The interpretive response to Question 1 of SAB Topic 14.D.1 notes that any relevant new or different information that would be useful should be incorporated into the estimate. Further, entities should “make good faith efforts to identify and use sufficient information in determining whether taking historical volatility, implied volatility or a combination of both into account will result in the best estimate of expected volatility” of the underlying share price.

Considerations related to estimating expected volatility may be summarized as follows:

- **Historical volatility** — Entities typically value employee stock options by using the historical volatility of the underlying share price. Under a closed-form model, such volatility is based on the most recent volatility of the share price over the expected term of the option; under a lattice model, it is based on the contractual term. ASC 718-10-55-37(a) states that an entity may disregard the volatility of the share price for an identifiable period if the volatility resulted from a condition (e.g., a failed takeover bid) specific to the entity and the condition is not expected to recur during the expected or contractual term. If the condition is not specific to the entity (e.g., general market declines), the entity generally would not be allowed to disregard or place less weight on the volatility of its share price during that period unless objectively verifiable evidence supports the expectation that market volatility will revert to a mean that will differ materially from the volatility during the specified period. The SEC staff believes that an entity's decision to disregard a period of historical volatility should be based on one or more discrete and specific historical events that are not expected to occur again during the term of the option. In addition, the entity should not give recent periods more weight than earlier periods.

  In certain circumstances, an entity may rely exclusively on historical volatility. However, because the objective of estimating expected volatility is to ascertain the assumptions that marketplace participants are likely to use, exclusive reliance may not be appropriate if there are future events that could reasonably affect expected volatility (e.g., a future merger that was recently announced).

- **Implied volatility** — The implied volatility of the underlying share price is not the same as the historical volatility of the underlying share price because it is derived from the market prices of an entity's traded options or other traded financial instruments with option-like features and not from the entity's own shares. Entities can use the Black-Scholes-Merton formula to calculate implied volatility by including the fair value of the option (i.e., the market price of the traded option) and other inputs (stock price, exercise price, expected term, dividend rate, and risk-free interest rate) in the calculation and solving for volatility. When valuing employee stock options, entities should carefully consider whether the implied volatility of a traded option is an appropriate basis for the expected volatility of the underlying share price. For example, traded options usually have much shorter terms than employee stock options, and the calculated implied volatility may not take into account the possibility of mean reversion. To compensate for mean reversion, entities use statistical tools for calculating a long-term implied volatility. For example, entities with traded options whose terms range from 2 to 12 months can plot the volatility of these options on a curve and use statistical tools to plot a long-term implied volatility for a traded option with an expected or a contractual term equal to an employee stock option.
Generally, entities that can observe sufficiently extensive trading of options and can therefore plot an accurate long-term implied volatility curve should place greater weight on implied volatility than on the historical volatility of their own share price (particularly if they do not meet the SEC’s conditions for relying exclusively on historical volatility). That is, a traded option’s volatility is more informative in the determination of expected volatility of an entity’s stock price than historical stock price volatility, since option prices take into account the option trader’s forecasts of future stock price volatility. In determining the extent of reliance on implied volatility, an entity should consider the volume of trading in its traded options and its underlying shares, the ability to synchronize the variables used to derive implied volatility (as close to the grant date of employee stock options as reasonably practicable), the similarity of the exercise prices of its traded options to its employee stock options, and the length of the terms of its traded options and employee stock options.

- **Limitations on availability of historical data** — Public entities should compare the length of time an entity’s shares have been publicly traded with the expected or contractual term of the option. A newly public entity may also consider the expected volatility of the share prices of similar public entities. In determining comparable public entities, the newly public entity would consider factors such as industry, stage of life cycle, size, and financial leverage. Nonpublic entities may also base the expected volatility of their share prices on the expected volatility of similar public entities’ share prices, and they may consider the same factors as those described above for a newly public entity. When a nonpublic entity is unable to reasonably estimate its entity-specific volatility or that of similar public entities, it may use a calculated value.

- **Data intervals** — An entity that considers the historical volatility of its share price when estimating the expected volatility of its share price should use intervals for price observations that (1) are appropriate on the basis of its facts and circumstances (e.g., given the frequency of its trades and the length of its trading history) and (2) provide a basis for a reasonable estimate of a fair-value-based measure. Daily, weekly, or monthly price observations may be sufficient; however, if an entity’s shares are thinly traded, weekly or monthly price observations may be more appropriate than daily price observations.

- **Changes in corporate and capital structure** — An entity’s corporate and capital structure could affect the expected volatility of its share price (e.g., share price volatility tends to be higher for highly leveraged entities). In estimating expected volatility, an entity should take into account significant changes to its corporate and capital structure, since the historical volatility of a share price for a period in which the entity was, for example, highly leveraged may not represent future periods in which the entity is not expected to be highly leveraged (or vice versa).

The SEC staff believes entities that have appropriate traded financial instruments from which they can derive an implied volatility should generally consider this measure. Further, depending on the extent to which these financial instruments are actively traded, more reliance or exclusive reliance on implied volatility may be appropriate because implied volatility reflects market expectations of future volatility.
SAB Topic 14.D.1 also addresses circumstances in which it is acceptable to rely exclusively on either historical volatility or implied volatility. To rely exclusively on historical volatility, an entity must:

- Have “no reason to believe that its future volatility over the expected or contractual term, as applicable, is likely to differ from its past.”
- Perform the computation by using a “simple average calculation method.”
- Use a “sequential period of historical data at least equal to the expected or contractual term . . . , as applicable.”
- Apply a “reasonably sufficient number of price observations . . . , measured at a consistent point throughout the applicable historical period.”
- Consistently apply this approach.

To rely exclusively on implied volatility, an entity must:

- Use a valuation model for employee stock options “that is based upon a constant volatility assumption.”
- Derive the implied volatility from “options that are actively traded.”
- Measure the “market prices . . . of both the traded options and underlying shares . . . at a similar point in time to each other and on a date reasonably close to the grant date of the employee share options.”
- Use traded options whose (1) exercise prices “are both . . . near-the-money and . . . close to the exercise price of the employee share options” and (2) “remaining maturities . . . are at least one year.”
- Consistently apply this approach.

If an entity is newly public or nonpublic, it may have limited historical data and no other traded financial instruments from which to estimate expected volatility. In such cases, as discussed in the SEC guidance in SAB Topic 14.D.1, it may be appropriate for the entity to base its estimate of expected volatility on the historical, expected, or implied volatility of comparable entities.

For more information on share-based compensation, see Deloitte’s *A Roadmap to Accounting for Share-Based Payment Awards*.

### 12.2.5 Liabilities, Equity, and Temporary Equity

**Example of an SEC Comment**

| You disclose that . . . you will be required to repurchase each share of Series B Convertible Preferred Stock that have not been converted into shares of common stock or automatically redeemed. Please tell us how you determined that your Series B Convertible Preferred Stock should be classified as mezzanine equity on your balance sheet and your consideration of the guidance in ASC 480-10-25-4. |

Life sciences entities pursuing an IPO often have complex financial instruments. The SEC historically has focused on the classification of liabilities and equity on the balance sheet when equity instruments have redemption provisions or financial instruments possess characteristics of both liabilities and equity. For example, classification of convertible debt instruments and freestanding warrants is often scrutinized since they may contain both liability and equity components under U.S. GAAP.
Prospective registrants may have previously outstanding instruments with characteristics of both liabilities and equity at the time they are approaching a potential IPO, or an entity may issue new instruments in connection with a potential IPO. Even if certain instruments are already outstanding before an IPO, when public financial statements are initially filed, it may be appropriate for an instrument to be classified outside of permanent equity in accordance with SEC rules. Further, for an entity that becomes publicly traded, there can be other accounting consequences that did not exist while the entity was private.

For more information about financial instruments, see Chapter 10 of this publication and Deloitte’s *A Roadmap to Distinguishing Liabilities From Equity*. 
Chapter 13 — Other Accounting and Financial Reporting Topics

13.1 Government Assistance

13.1.1 On the Horizon — Proposed ASU on Disclosures by Business Entities About Government Assistance

In November 2015, the FASB issued a proposed ASU on disclosures about government assistance received by entities. As explained in the proposed ASU, the proposal’s objective is “to increase transparency about government assistance arrangements including (1) the types of arrangements, (2) the accounting for government assistance, and (3) their effect on an entity’s financial statements.” Comments were due by February 10, 2016, and the Board received approximately 40 comment letters.

13.1.1.1 Background

There is no explicit guidance under current U.S. GAAP on the recognition, measurement, or disclosure of government assistance. As a result, there is diversity in practice related to how business entities account for, and disclose information about, government assistance arrangements.

The proposed ASU would apply to all entities, other than NFPs within the scope of ASC 958, that enter into a “legally enforceable agreement with a government to receive value.” However, the proposed ASU states that it would not apply to transactions in which the government is either (1) “[l]egally required to provide a nondiscretionary level of assistance to an entity simply because the entity meets the applicable eligibility requirements that are broadly available without specific agreement between the entity and the government” or (2) “[s]olely a customer” of the entity.

13.1.1.2 Key Provisions

Under the proposal, entities would be required to disclose in their annual financial statements information about the nature of the assistance, related accounting policies, and the effect on the financial statements, including:

- A “general description of the significant categories (for example, grants, loans, or tax incentives) and the form in which the assistance has been received (for example, as a reduction of an expense, a refund of taxes paid, free resources, or a cash grant).”

- “The accounting policy used to account for government assistance (for example, whether assistance is recognized immediately into income or recognized over the life of a related asset).”

- The financial statement line items “affected by government assistance (for example, whether the assistance has been deducted from the carrying value of an asset or presented as a performance obligation liability) and the amounts applicable to each line item.”

- “Unless impracticable, the amount of government assistance received but not recognized directly in the financial statements.”
The proposed ASU would also require entities to disclose the significant terms and conditions of the agreement, including its duration or period, the tax rate or interest rate provided in the agreement, the commitments made by each party, the provisions (if any) for recapturing government assistance, and any other contingencies.

13.1.1.3 Redeliberations and Next Steps

After the comment period closed, the FASB began redeliberations on the basis of stakeholder feedback. The FASB staff plans to focus on scope, disclosure requirements for amounts not recognized directly in the financial statements, restrictions, transition and effective date, private-company considerations, and overall costs and benefits of the disclosures.

At the FASB's November 14, 2018, meeting, the Board affirmed its decision on the effective date and scope of the final ASU. As stated in the FASB's tentative Board decisions, the final ASU would be effective for fiscal years ending after December 15, 2020, for PBEs and fiscal years ending after December 15, 2021, for non-PBEs (i.e., private companies). Early adoption would be permitted. Further, the final ASU “should be applied on a modified prospective basis in the first set of financial statements following the effective date to agreements that are either (1) existing at the effective date or (2) entered into after the effective date. Retrospective application also is permitted.” The Board also “decided that the scope of the amendments would apply to grants of assets, tax assistance, low-interest-rate loans, loan guarantees, and forgiveness of liabilities.” In addition, the Board “affirmed its decision that the disclosure requirements for [PBEs] and private companies would be the same.”

Further, the Board “directed the staff to draft a final [ASU] and perform additional outreach with stakeholders for the staff to bring to another meeting to address the feedback, any sweep issues, and the costs and benefits of the amendments.” The Board will continue its redeliberations at a future meeting.

Connecting the Dots

Entities in the life sciences industry have historically benefited domestically and internationally from a wide variety of government assistance programs. Although the scope of the FASB's project related to government assistance is limited to disclosures, the final ASU that is ultimately issued may still require significant effort to track a vast array of arrangements and provide the appropriate level of disclosure. Life sciences entities should continue to monitor the progress of the project and consider whether systems or other changes will be needed to gather the required information.

13.2 Inventory

13.2.1 On the Horizon — Proposed ASU on Disclosure Requirements for Inventory

13.2.1.1 Background

In January 2017, the FASB issued a proposed ASU that would modify or eliminate certain disclosure requirements related to inventory as well as establish new requirements. Comments on the proposed ASU were due by March 13, 2017.

The proposal is part of the FASB's disclosure framework project, which, as explained on the Board's related Project Update page, is intended “to improve the effectiveness of disclosures in notes to financial statements by facilitating clear communication of the information required by generally accepted accounting principles (GAAP) that is most important to users of each entity's financial statements.”
In March 2014, the FASB issued a proposed Concepts Statement on Chapter 8 of its conceptual framework for financial reporting. The Board later decided to test the proposed Concepts Statement by considering the effectiveness of financial statement disclosures related to inventory, income taxes, fair value measurements, and defined benefit pension and other postretirement plans. The proposed ASU is the result of the application of the proposed Concepts Statement to inventory. For more information about the proposed ASU, see Deloitte’s January 12, 2017, Heads Up.

**Connecting the Dots**

Also as part of its disclosure framework project, the FASB proposed guidance in July 2016 that would amend disclosure requirements related to income taxes. See Deloitte’s July 29, 2016, Heads Up for more information. Further, in August 2018, the FASB issued ASUs 2018-13 and 2018-14, which amend the disclosure requirements related to fair value measurements and defined benefit pension and other postretirement plans, respectively. See Deloitte’s August 29 and August 31, 2018, Heads Up newsletters for more information.

The proposed ASU notes that the objective of the inventory disclosures in ASC 330 is to give financial statement users information that would help them assess how future cash flows may be affected by:

- Different types of inventory.
- The use of differing methods to measure inventory balances.
- Transactions, events, and circumstances that are outside the entity’s normal course of business.

### 13.2.1.2 Key Provisions

#### 13.2.1.2.1 Materiality

The proposed ASU notes that entities would not be required to provide inventory disclosures if such disclosures are immaterial. For guidance on making that determination, the proposed ASU refers entities to ASC 235-10-50-7 through 50-9, which would be added by the FASB’s proposed ASU on assessing whether disclosures are material. For additional information about the proposed ASU on materiality, see Deloitte’s September 28, 2015, Heads Up and its November 13, 2017, journal entry.

#### 13.2.1.2.2 Disclosure of Changes in Inventory

The Board considered several approaches for disclosing changes in inventory, including (1) a detailed rollforward of the inventory balance in tabular format; (2) disclosure of significant changes in the balance that are not attributable to the purchase, manufacture, and sale of inventory in the normal course of business; and (3) a hybrid approach that would combine both methods depending on the significance of an entity’s inventory. Because the Board believes that the rollforward and hybrid approaches would most likely be too costly and difficult for entities to implement, the proposed ASU would require all entities to disclose significant changes in inventory resulting from transactions or events other than the purchase, manufacture, or sale of inventory in the normal course of business.

The following are examples of such changes:

- “Atypical losses from the subsequent measurement of inventory or shrinkage, spoilage, or damage and a description of the facts and circumstances leading to those losses.”
- “Balance sheet reclassifications.”

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1 The proposed Concepts Statement was finalized in August 2018.
• “Inventory obtained through a business combination” or “disposed of through a divestiture.”
• “Unrealized gains and losses for inventories recorded above cost or at selling prices.”

The proposed ASU includes an illustrative example of how an entity would disclose changes in inventory.

13.2.1.2.2.1 Composition of Inventory
In addition to total inventory, the proposed ASU would require all entities to disclose the inventory’s major components. That is, entities would disclose the composition of inventory such as raw materials, work in process, finished goods, and supplies. Under the proposed ASU’s amendments, an entity would also be required to (1) provide “a qualitative description of the types of costs it capitalizes into inventory” and (2) the basis it uses to measure its inventory as well as the amount recorded under each basis.

Further, an entity that reports inventory on a last in, first out (LIFO) basis would be excluded from the requirement if it were to conclude that it is impracticable to allocate the LIFO reserve to inventory components. That is, an entity would be permitted to disclose inventory components under another cost basis — such as first in, first out (FIFO) — and reconcile such components to the ending aggregate LIFO inventory balance with the aggregate LIFO reserve.

13.2.1.2.2.2 Inventory Reported Under the LIFO Cost Flow Assumption
Besides adding the measurement alternative discussed above, the proposed ASU would codify LIFO-related disclosures that SEC registrants are currently required to provide. In addition, paragraph BC49 of the proposal notes that other entities include similar disclosures in their financial statements on the basis of recommendations in a 1984 AICPA Issues Paper. Consequently, the Board proposes to add ASC 330-10-50-13, which would require all entities that apply the LIFO method to disclose (1) the excess of replacement cost or current cost over the reported inventory amount and (2) the effect on net income of the liquidation of a portion of an entity’s LIFO inventory.

Connecting the Dots
In the proposed ASU’s Basis for Conclusions, the FASB observed that the cost to implement the guidance should be minimal because many entities reporting inventory under LIFO are likely to be providing the proposed disclosures already.

13.2.1.2.2.3 Other Inventory Disclosures
For entities that use standard costs to measure inventory, the proposed ASU would update ASC 330-10-30-12 to eliminate the requirement to describe the relationship between standard costs and costs computed under another recognizable inventory measurement basis. This disclosure was seen as redundant because as long as standard costs are updated at reasonable intervals, the revised standard costs should approximate another acceptable inventory measurement basis, such as FIFO or average costs.

13.2.1.2.2.4 Segment Disclosures for PBEs
For PBEs, the proposed ASU would amend ASC 280-10-50-25 to add (1) inventory disclosures by reportable segment and (2) a reference to a related example (Example 4) that would be codified in ASC 280-10-55-53 and 55-54. Specifically, if inventory balances are included in (1) the determination of segment assets that the chief operating decision maker (CODM) reviews or (2) information that the

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CODM regularly reviews (even if such balances are not included in the determination of segment assets), PBEs would be required to disclose the following by reportable segment:

- Total inventory.
- A disaggregation of inventory by major component (such as raw materials, work in process, finished goods, and supplies).

In addition, inventory or a major component of inventory that has not been allocated to a reportable segment would be classified as unallocated.

A PBE would also be required to provide similar disclosures in its interim financial statements if the criteria in ASC 280-10-50-25 are met (i.e., inventory balances are included in the determination of segment assets, or the CODM reviews information that includes inventory balances).

**Connecting the Dots**

Only the information reviewed by the CODM would need to be disclosed on an interim basis. As illustrated in Example 4 of the proposed ASU (specifically, in ASC 280-10-55-54 as proposed), if the CODM reviews inventory by segment in total but does not regularly review information about inventory for each component by segment, an entity would be required to disclose only total inventory by segment in its interim financial statements.

**13.2.1.3 Scope, Transition, and Effective Date**

The proposed ASU would affect only inventory disclosures under ASC 330 for all entities (i.e., the proposal would not affect disclosures related to cost of goods sold). The guidance would be applied prospectively, and the Board will determine an effective date and whether to permit early adoption after it considers feedback from stakeholders on the proposal.

**Connecting the Dots**

On June 21, 2017, the Board held a meeting to discuss a summary of the comments received on the proposed ASU. No decisions were made during the meeting. The Board directed the staff to conduct additional outreach and research on the proposed disclosure requirements related to changes to the inventory balance. The Board asked the staff to consider (1) the application of those proposed disclosures to companies engaged in manufacturing and wholesale businesses and (2) the needs of financial statement users in such industries. The Board also asked the staff to present a plan for redeliberations collectively with the other disclosure framework projects at a future meeting.

**13.3 Common-Control Transactions**

As life sciences entities seek to balance their portfolio and potentially prepare for public offerings, they may engage in a variety of common-control transactions. A common-control transaction is a transfer of net assets or an exchange of equity interests between entities under the control of the same parent. Such a transaction is similar to a business combination for the entity that receives the net assets or equity interests; however, the transaction does not meet the definition of a business combination because there is no change in control over the net assets by the parent. Therefore, the accounting and reporting for a transaction between entities under common control is outside the scope of the business combinations guidance in ASC 805-10, ASC 805-20, and ASC 805-30 and is addressed in the “Transactions Between Entities Under Common Control” subsections of ASC 805-50. Since there is no change in control over the net assets from the parent’s perspective, there is no change in basis in the net assets. ASC 805-50 requires the receiving entity to recognize the net assets received at their historical carrying amounts, as reflected in the parent’s financial statements.
Chapter 13 — Other Accounting and Financial Reporting Topics

For more information and interpretive guidance on common-control transactions, see Appendix B of Deloitte’s *A Roadmap to Accounting for Business Combinations*.

### 13.4 Discontinued-Operations Reporting

While many life sciences entities have sought ways to expand their pipeline of products in development or to acquire additional commercial products, others have explored how to generate additional returns on assets that are no longer a strategic focus. When an entity sells a business or product line, questions often arise about whether the divested group of assets should be reported as a discontinued operation. An entity will need to use judgment when making this determination. The entity’s conclusion will be based on whether the disposition represents a strategic shift to the entity and whether the disposal will have a major effect on the entity’s operations and financial results.

For more information about discontinued-operations reporting, including interpretations of the accounting guidance on the topic, see Deloitte’s *A Roadmap to Reporting Discontinued Operations*.

### 13.5 Carve-Outs

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

“Carve-out financial statements” is a general term used to describe financial statements derived from the financial statements of a larger parent entity. The form of those financial statements may vary, however, depending on the situation. For example, if the acquisition is small, a strategic buyer of a carve-out entity may be satisfied with an unaudited balance sheet and income statement for the most recent fiscal year. Another public buyer, however, may require a full set of SEC-compliant audited financial statements, including footnotes, for the three most recent fiscal years. Further, a third buyer may require that the periods be audited but may not be concerned with SEC reporting considerations. The existence of a foreign buyer could present different requirements and challenges in addition to those noted above, such as working closely with the foreign buyer on IFRS conversion of certain financial statement line items. The purpose of the financial statements also greatly affects the timeline, since carve-out financial statements filed for a public spin-off via Form 10³ would need to be available at least 60 days before the spin-off, while carve-out financial statements prepared for compliance with SEC Regulation S-X, Rule 3-05,⁴ would need to be available within 75 days post-closing.

Accordingly, assessing the potential audience is critical to understanding the basis of presentation, the periods of financial information required, and the level of effort and organizational focus that may be necessary to meet the needs of the potential transaction. Such an assessment can be particularly difficult when the carve-out financial statements are being prepared before any potential buyers are identified or when the potential buyer pool is numerous or diverse.

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³ A Form 10 is the spin-off equivalent of a Form S-1 filed by new registrants in connection with an IPO.
⁴ Public buyers have to comply with SEC Regulation S-X, Rule 3-05, which requires them to provide financial statements for significant acquisitions. The significant acquisition rules focus on three principal criteria: the investment test, the asset test, and the income test. If the results of any of those tests exceed a threshold of 20 percent, at least one audited period (and potentially up to three such periods if the results of any of the tests exceed a threshold of 50 percent) will be required.
13.5.1 Management Considerations

Preparing carve-out financial statements can be challenging and often requires management to use judgment and carefully plan ahead. Below are some considerations management should take into account when preparing carve-out financial statements.

13.5.1.1 Assembling the Right Team

Involving the appropriate personnel is an integral step in planning for carve-out transactions. Management should evaluate which employees could help provide the information needed to prepare accurate and complete financial statements. Such employees may include those in the operations or human resources departments. In addition, management may need to engage external specialists (e.g., accounting advisory, tax, legal, or valuation specialists).

13.5.1.2 Materiality and Evaluating Misstatements

Because the materiality thresholds related to the carve-out financial statements will most likely be lower than those of the consolidated parent entity, management may need to assess accounts and balances of the carve-out entity more closely than it had as part of preparing the financial statements of the parent. Passed misstatements and disclosures previously considered immaterial to the parent's financial statements that are related to the carve-out entity would need to be reconsidered on the basis of materiality thresholds applicable to the carve-out financial statements. Further, the effects of transition adjustments related to the adoption of new accounting standards that may have been immaterial in the parent entity's financial statements may be material in the carve out entity's financial statements.

13.5.1.3 Internal Controls

Management should design and implement processes and controls for preparing the carve-out financial statements (e.g., management may need to design, implement, and execute controls related to the appropriate determination and recording of income statement and balance sheet allocations to the carve-out financial statements). Although an entity may often be able to leverage existing financial statement preparation controls, management should evaluate whether it needs to (1) modify such controls to accommodate process changes related to preparing the carve-out financial statements and (2) ensure that any other controls related to preparing the parent company financial statements are sufficiently direct and precise.

In addition to controls related to the carve-out entity, management may need to consider controls for its future status as either a public or a private company. Typically, consideration of such future controls affords management an opportunity to reevaluate the control structure to ensure that it is most efficient and effective for the new company going forward or that it aligns with the controls of a purchaser.

13.5.1.4 Supporting Documentation

Management should consider the type of documentation necessary to support the assumptions made and results achieved in preparing carve-out financial statements. In some cases, the supporting documentation may already exist (e.g., compensation expense is usually calculated and allocated on an employee-by-employee basis). However, management may need to develop and maintain new documentation for the allocations made for the carve-out financial statements (e.g., a rational and systematic method for allocating selling, general, and administrative expenses).

Management may choose to use existing accounting systems as much as possible when preparing carve-out financial statements. The use of existing accounting systems may be limited, however, depending on the level of detail at which the account balances are maintained as well as the structure
of the carve-out entity (e.g., whether the carve-out represents a segment of the parent or only part of a segment). If the carve-out entity represents a segment or component for which discrete financial information is readily available, management may be able to readily extract information from its existing accounting records. However, if the carve-out entity includes portions of different segments, further involvement of IT specialists may be required. Multiple periods of carve-out financial statements may be required throughout the registration statement process given that financial statements may become stale. Historical periods may include additional complexities for documentation and support depending on whether historical acquisitions occurred during those periods.

13.5.1.5 Working With Auditors

If, as part of the preparation of carve-out financial statements, external auditors need to perform an audit and issue an audit opinion, they will need to understand the process undertaken by management for collecting and maintaining all supporting documentation used in the preparation of the carve-out financial statements. For balances in which judgment or complex estimates are required, management should ensure that its documentation contains enough detail for auditors to reach conclusions about the reasonableness of the amounts allocated to, and balances presented in, the carve-out financial statements. Typically, the audit scope could widen and the number of audit procedures could increase if controls over the carve-out financial statements cannot be relied upon.

13.5.2 Regulatory Considerations

In addition to defining the business and financial information required and determining the specific approach to the preparation of the financial information, management should consider any regulatory restrictions that may exist related to the divestiture of a business or the transfer of contracts to the buyer. For example, it is common in the life sciences industry for operations in a specific country to have a delayed closing whereby one or more elements of the business do not fully transfer to a buyer at the time of the divestiture. The delays are frequently linked to jurisdictional requirements for the buyer to obtain the marketing authorizations needed to distribute pharmaceutical products or to negotiate changes to government contracts when nontransferable tender agreements exist. Management may need to (1) determine which statutory financial statements are required and (2) consider the audit of those financial statements.

When transitional services agreements are put in place, management should also consider the financial reporting treatment of any activities performed by the seller on behalf of the buyer and how profits earned during the period that are transferred to the buyer should be reported.

13.5.3 “RemainCo” Considerations

Carve-out financial statements typically include an allocation of corporate costs to the business to be divested, such as those related to executive management, IT, tax, insurance, accounting, legal and treasury services, and certain employee benefits. Upon the disposal, the individuals performing these activities may not transfer to the divested business. As a result, the remaining business would retain these “stranded costs.”

The parent entity is required under ASC 205-20 to evaluate whether the effect of a disposal resulting from a carve-out transaction is to be presented as a discontinued operation. Depending on the form of the carve-out transaction, this evaluation may occur when (1) the carve-out entity meets the criteria in ASC 205-20-45-1E to be classified as held for sale, (2) the carve-out entity is disposed of by sale, or (3) the carve-out entity is disposed of other than by sale in accordance with ASC 360-10-45-15 (e.g., by abandonment or in a distribution to owners in a spin-off). If the disposal meets the conditions for the parent entity to report it as a discontinued operation, it would be unlikely that amounts
presented as discontinued operations for the disposal in the parent-entity financial statements would equal the operations reflected in the carve-out entity's financial statements (e.g., because of differences between how expenses may have been allocated in the carve-out financial statements and how expenses associated with the discontinued operation are determined). See Section 13.4 of this publication and Deloitte's *A Roadmap to Reporting Discontinued Operations* for further information.

Management's determination that a portion of the carve-out entity's operations should be presented in discontinued operations will also affect the carve-out entity's statement of cash flows. See Section 3.3 of Deloitte's *A Roadmap to the Preparation of the Statement of Cash Flows* for further discussion.

For more information and interpretive guidance on preparing carve-out financial statements, see Deloitte's *A Roadmap to Accounting and Financial Reporting for Carve-Out Transactions*.

### 13.6 Cost of Doing Business

#### 13.6.1 Introduction

The life sciences industry has been subject to increased regulation in recent years at both the federal and state level, particularly as overall pharmaceutical profits and sales of opioid-based products have come under closer scrutiny. In some cases, fees have been imposed on industry participants as a result. Two examples, which are discussed below, are (1) the branded prescription drug (BPD) fee under the federal Patient Protection and Affordable Care Act and (2) the surcharge imposed on opioid manufacturers, distributors, and importers under the state of New York's Opioid Stewardship Act.

#### 13.6.2 Branded Prescription Drug Fee

##### 13.6.2.1 Background

The federal Patient Protection and Affordable Care Act imposes an annual fee on the pharmaceutical manufacturing industry for each calendar year beginning on or after January 1, 2011. An entity's portion of the annual fee is payable no later than September 30 of the applicable calendar year and is not tax deductible. The portion of the annual fee that is allocated to individual entities is determined on the basis of the amount of an entity's BPD sales for the current year as a percentage of the industry's BPD sales for the same period.

A pharmaceutical manufacturing entity's portion of the annual fee becomes payable to the U.S. Treasury once the entity has a gross receipt from BPD sales to any specified government program or in accordance with coverage under any government program for each calendar year beginning on or after January 1, 2011.

ASU 2010-27 (codified in ASC 720-50) provides guidance on accounting and reporting related to the BPD annual fee. ASC 720-50-25-1, which was added by ASU 2010-27 and subsequently amended by ASU 2011-06, states, in part:

> The liability related to the annual fee described in paragraphs 720-50-05-1 through 05-4 shall be estimated and recorded in full upon the first qualifying sale for pharmaceutical manufacturers . . . in the applicable calendar year in which the fee is payable with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. [Emphasis added]
On July 28, 2014, the IRS issued final regulations related to the BPD fee that contain a new term, “covered entity status” (see definition and related example below). The final regulations indicate that an entity’s obligation to pay its portion of the BPD fee in any given calendar year is not triggered by the first qualifying sale in that calendar year but is triggered instead by the qualifying sales in the previous year.

On the basis of a discussion with the SEC staff, the accounting for the BPD fee should be based on the final IRS regulations, which require an entity to recognize expense for the BPD fee as qualifying sales occur. Further, the staff indicated that it would not object if an entity continued to apply the income statement presentation guidance in ASC 720-50-45-1, which requires the BPD fee to be presented as an operating expense.

### 13.6.2.2 Definition of Covered Entity Status

Section 51.2(e)(5) of the final IRS regulations defines covered entity status as follows:

(i) **Rule.** An entity’s status as a covered entity begins in the first fee year in which the entity has branded prescription drug sales and continues each subsequent fee year until there are no remaining branded prescription drug sales for that entity to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e).

(ii) **Example.** The following example illustrates the rule of paragraph (e)(5)(i) of this section:

(A) **Facts.** Entity A is a manufacturer with gross receipts of more than $5 million from branded prescription drugs sales in 2011. Entity A does not have any gross receipts from branded prescription drug sales before or after 2011.

(B) **Analysis.** Entity A is a covered entity beginning in 2011 because it had gross receipts from branded prescription drug sales in 2011. For the 2011 fee year, Entity A does not owe a fee because the 2011 fee is based on sales data from the 2009 sales year. For the 2012 fee year, Entity A does not owe a fee because the 2012 fee is based on sales data from the 2010 sales year. Entity A continues to be a covered entity for the 2012 fee year because its branded prescription drug sales from the 2011 sales year have not yet been taken into account as described in §51.5(c) and used to calculate the adjustment amount described in §51.5(e). For the 2013 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales from the 2011 sales year are taken into account as described in §51.5(c) for purposes of computing the 2013 fee. For the 2013 fee year, Entity A is also liable for the adjustment amount described in §51.5(e) for the difference between its 2012 fee computed using sales data from the 2010 sales year, which is $0, and what the 2012 fee would have been using sales data from the 2011 sales year. For the 2014 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales for the 2011 sales year are used to calculate the adjustment amount described in §51.5(e). Therefore, for the 2014 fee year, Entity A will receive an adjustment amount for the difference between its 2013 fee computed using sales data from the 2011 sales year, and what the 2013 fee would have been using sales data from the 2012 sales year, which is $0. After the 2014 fee year, there are no remaining branded prescription drug sales to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e) for Entity A. Accordingly, Entity A is not a covered entity after the 2014 fee year.

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5 TD 9684, Branded Prescription Drug Fee.
13.6.3 New York State Opioid Stewardship Act

In April 2018, the Opioid Stewardship Act was enacted in the state of New York, with an effective date of July 1, 2018. The Act establishes a program in which manufacturers, distributors, and importers of certain opioid controlled substances licensed by the New York State Department of Health (the “licensees”) are collectively required to contribute $100 million annually to a fund to aid in the fight against the opioid epidemic. The Act provides that licensees are to report transaction information for opioids sold or distributed in the state of New York (subject to an exemption list published by the state). The state will then determine each licensee’s market share percentage of total opioids sold and distributed in the state to calculate the licensee’s share of the $100 million. Determinations are based on the initial transaction in the distribution chain when opioids are first sold or distributed in the state. The market share calculation to be performed is based on morphine milligram equivalents. The payment for 2017 applicable sales transactions was due on January 1, 2019.

However, on December 19, 2018, in an adjudication of civil claims brought by a trade association of pharmaceutical distributors, a trade association of pharmaceutical manufacturers, and a pharmaceutical manufacturer to challenge the constitutionality of the Act, the U.S. District Court for the Southern District of New York ruled in favor of the plaintiffs and enjoined enforcement of the Act. In light of the court’s ruling, companies that otherwise would be subject to the requirements of the Act are encouraged to consult with their legal and accounting advisers to determine how the ruling applies to their particular facts and circumstances.

13.7 Going Concern

13.7.1 Introduction

Much of the life sciences industry consists of small, research-focused private biotechnology firms that represent an important source of innovation. These firms are generally focused on a specific technology platform, a mechanism of action, or a handful of early-stage compounds, and many of these firms are not profitable or do not have commercial revenue streams. Given the substantial costs and timelines associated with biopharmaceutical R&D, attracting and sustaining investment remains an ongoing challenge. This landscape requires many life sciences entities to evaluate the going-concern uncertainty in their financial statements.

ASU 2014-15 (the “going-concern standard,” codified in ASC 205-40) provides guidance on how to determine when and how to disclose going-concern uncertainties in the financial statements. The going-concern standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Under the standard, an entity must provide certain disclosures if conditions or events “raise substantial doubt about the entity’s ability to continue as a going concern.”

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6 An entity that is neither an SEC filer nor a conduit bond obligor for debt securities that are traded in a public market would use the date on which the financial statements are available to be issued (in a manner consistent with the going-concern standard’s definition of the term “financial statements are available to be issued”).
13.7.2 Disclosure Threshold

An entity is required to disclose information about its potential inability to continue as a going concern when there is “substantial doubt” about its ability to continue as a going concern, which the going-concern standard defines as follows:

Substantial doubt about an entity’s ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The term probable is used consistently with its use in Topic 450 on contingencies.

When applying this disclosure threshold, entities are required to evaluate “relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued.” Reasonably knowable conditions or events are those that can be identified without undue cost and effort.

The going-concern standard provides the following examples of events that suggest that an entity may be unable to meet its obligations:

a. Negative financial trends, for example, recurring operating losses, working capital deficiencies, negative cash flows from operating activities, and other adverse key financial ratios
b. Other indications of possible financial difficulties, for example, default on loans or similar agreements, arrearages in dividends, denial of usual trade credit from suppliers, a need to restructure debt to avoid default, noncompliance with statutory capital requirements, and a need to seek new sources or methods of financing or to dispose of substantial assets
c. Internal matters, for example, work stoppages or other labor difficulties, substantial dependence on the success of a particular project, uneconomic long-term commitments, and a need to significantly revise operations
d. External matters, for example, legal proceedings, legislation, or similar matters that might jeopardize the entity’s ability to operate; loss of a key franchise, license, or patent; loss of a principal customer or supplier; and an uninsured or underinsured catastrophe such as a hurricane, tornado, earthquake, or flood.

13.7.3 Time Horizon

In each reporting period (including interim periods), an entity is required to assess its ability to meet its obligations as they become due for one year after the date the financial statements are issued or available to be issued.7

7 See footnote 4.
13.7.4 Disclosure Content

If an entity triggers the substantial-doubt threshold, its footnote disclosures must contain the following information, as applicable:

<table>
<thead>
<tr>
<th>Substantial Doubt Is Raised but Is Alleviated by Management’s Plans</th>
<th>Substantial Doubt Is Raised and Is Not Alleviated</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Principal conditions or events.</td>
<td>• Principal conditions or events.</td>
</tr>
<tr>
<td>• Management’s evaluation.</td>
<td>• Management’s evaluation.</td>
</tr>
<tr>
<td>• Management’s plans.</td>
<td>• Management’s plans.</td>
</tr>
<tr>
<td>• Statement that there is “substantial doubt about the entity’s ability to continue as a going concern.”</td>
<td></td>
</tr>
</tbody>
</table>

The going-concern standard explains that these disclosures may change over time as new information becomes available and that disclosure of how the substantial doubt was resolved is required in the period in which substantial doubt no longer exists (before or after consideration of management’s plans). In addition, the going-concern standard states that the mitigating effects of management’s plans to alleviate substantial doubt should be evaluated only if (1) the plans are approved before the financial statement issuance date and (2) both of the following conditions are met:

a. It is probable that management’s plans will be effectively implemented within one year after the date that the financial statements are issued.

b. It is probable that management’s plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued.

13.8 Health Tech

The health tech marketplace is a high-growth environment in which participants (i.e., life sciences companies, health care providers, and health plans) provide technology and service solutions to a wide spectrum of stakeholders across all of the traditional sectors in the life sciences and health care industry. These companies may provide clinical decision support, drug discovery/bioinformatics software, health care administration software, and medical imaging software. They may also offer other products or services, including clinical trial database management, decision support tools for drug discovery, online marketplaces for pharmaceuticals R&D, medicinal prediction using artificial intelligence, and Web-based simulation for R&D.

Tech companies are disrupting long-standing business models and methods of health care delivery as well as sources of health information and ways to access it. The interconnectedness of that ecosystem — its strength driven in part by technology — is increasingly likely to become a key factor affecting operational and financial performance of the industry as a whole. In addition, upstarts can be expected to appear wherever there is friction in the health care ecosystem. The disruption caused by technology-driven entrants to the health care industry appears to be creating significant opportunities for incumbents to reinvent themselves, for entrepreneurs and investors to carve out new spaces in the market, and for nontraditional companies to enter the space and grow. As a result, well-funded health tech companies continue to emerge, fueled by the expanding flow of private equity, strategic, and venture capital funding.
Much of the interpretive guidance in this publication is likely to be applicable to companies in the health tech sector. Further, given the development and use of software in connection with the product/service offerings within the health tech space, some of the more narrow-scope considerations related to software with respect to capitalization of costs and recognition of revenue that have historically been the focus of more traditional software companies could be of importance to companies operating in this space. Accordingly, the table below references recent standard-setting activity as well as interpretive guidance for certain software issues that companies in the health tech sector may find helpful. Some of the guidance was developed by the AICPA’s Software Entities Revenue Recognition Task Force, which was one of 16 AICPA industry task forces that helped develop the AICPA Audit and Accounting Guide Revenue Recognition (the “AICPA Revenue Guide”). The AICPA Revenue Guide contains guidelines on how to apply the new revenue standard to various industries. See the AICPA’s Web site for status updates and further information about the software entities task force.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Title</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Challenges Associated With Applying the New Revenue Standard: Establishing the Stand-Alone Selling Price as a Range”</td>
<td>Deloitte’s December 14, 2018, Technology Alert</td>
</tr>
<tr>
<td></td>
<td>“Stand-Alone Selling Price of Postcontract Support Based on a Stated Renewal Percentage”</td>
<td>Q&amp;A 7-1 of Deloitte’s A Roadmap to Applying the New Revenue Recognition Standard (the “Revenue Roadmap”)</td>
</tr>
<tr>
<td></td>
<td>“Different Stand-Alone Selling Price for the Same Good or Service in a Single Contract”</td>
<td>Q&amp;A 7-2 of Deloitte’s Revenue Roadmap</td>
</tr>
<tr>
<td></td>
<td>“Different Selling Price for the Same Product to Different Customers”</td>
<td>Q&amp;A 7-3 of Deloitte’s Revenue Roadmap</td>
</tr>
<tr>
<td></td>
<td>“FASB Amends Guidance on Cloud Computing Arrangements”</td>
<td>Deloitte’s September 11, 2018, Heads Up</td>
</tr>
<tr>
<td>Termination rights</td>
<td>“Challenges Associated with Applying the New Revenue Standard: Termination Rights”</td>
<td>Deloitte’s July 24, 2018, Technology Alert</td>
</tr>
<tr>
<td>Refund liabilities</td>
<td>“Classification and Presentation of Refund Liabilities”</td>
<td>Q&amp;A 13-1A of Deloitte’s Revenue Roadmap</td>
</tr>
</tbody>
</table>
13.9 PCAOB Changes to the Auditor’s Report — Critical Audit Matters

In June 2017, the PCAOB adopted a new auditing standard on the auditor’s report (the “standard” or “release”). While retaining the current “pass/fail” opinion of the existing auditor’s report, the standard includes several significant modifications, including the introduction of critical audit matters (CAMs), all of which are intended to increase the informational value, usefulness, and relevance of the auditor’s report.

13.9.1 Critical Audit Matters

A CAM is defined in the standard as “any matter arising from the audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex auditor judgment.”

The standard includes a nonexclusive list of factors for the auditor to take into account, alone or in combination, in determining whether a matter involved especially challenging, subjective, or complex auditor judgment.

CAMs will be identified and described in a separate section in the auditor’s report titled “Critical Audit Matters.” Specific language will precede the description of the CAMs, stating that (1) CAMs do not alter the opinion on the financial statements and (2) the auditor is not providing a separate opinion on the CAMs or the accounts or disclosures to which they relate. The release states that for each CAM communicated in the auditor’s report, the auditor will be required to:

- “Identify the [CAM].”
- “Describe the principal considerations that led the auditor to determine that the matter is a [CAM].”
- “Describe how the [CAM] was addressed in the audit.”
- “Refer to the relevant financial statement accounts or disclosures that relate to the [CAM].”

The release also states that the determination of a CAM “should be made in the context of [a] particular audit, with the aim of providing audit-specific information rather than a discussion of generic risks.” It is expected that in most audits to which the CAM requirements apply (see applicability information below), the auditor would identify at least one CAM. If no CAMs are identified, the auditor would be required to make a statement to that effect in the auditor’s report.
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The chart below, which is adapted from the release, illustrates the auditor’s decision process for identifying and communicating CAMs.

**Steps the auditor takes to identify CAMs:**
1. Start with the matters communicated or required to be communicated to the audit committee.
2. Identify those matters that:
   a. Relate to accounts or disclosures that are material to the financial statements.
   b. Involved especially challenging, subjective, or complex auditor judgment.

**For each CAM communicated in the auditor’s report, the auditor must:**
- Identify the CAM.
- Describe the principal considerations that led to the auditor’s determination that the matter is a CAM.
- Describe how the CAM was addressed in the audit.
- Refer to the relevant financial statement accounts or disclosures that relate to the CAM.

**Factors to take into account when determining whether a matter involved especially challenging, subjective, or complex auditor judgment:**
- The auditor’s assessment of the risks of material misstatement, including significant risks.
- The degree of auditor judgment related to areas in the financial statements that involved the application of significant judgment or estimation by management, including estimates with significant measurement uncertainty.
- The nature and timing of significant unusual transactions and the extent of audit effort and judgment related to these transactions.
- The degree of auditor subjectivity in applying audit procedures to address the matter or in evaluating the results of those procedures.
- The nature and extent of audit effort required to address the matter, including the extent of specialized skill or knowledge needed or the nature of consultations outside the engagement team regarding the matter.
- The nature of audit evidence obtained regarding the matter.

**13.9.2 Effective Date**

The effective date for CAMs is being phased in as follows:
- Audits of large accelerated filers (as defined by the SEC): fiscal years ending on or after June 30, 2019.
- Audits of all other companies: fiscal years ending on or after December 15, 2020.

However, the release states that auditors may elect to comply with the standard before its effective date at any point after SEC approval.

Communication of CAMs is not required for audits of emerging growth companies as defined in Section 3(a)(80) of the Securities Exchange Act of 1934. However, the standard permits voluntary inclusion of CAMs in the auditor’s report for such entities.
13.9.3 Considerations for Auditors, Management, and Audit Committees

Although the standard will be implemented in accordance with phased-in effective dates, management and audit committees will most likely want to start to consider the implications of the new requirements. Auditors are encouraged to engage with management and the audit committee in advance of the related effective dates to discuss the types of matters that may be communicated as CAMs in future audit reports.

Potential questions regarding CAMs may include the following:

- What matters could be CAMs?
- How will management and audit committees engage with the auditor as CAMs are identified and the auditor’s descriptions of the CAMs are developed and finalized?
- How will the timing of auditor communications with management and the audit committee accommodate the discussion of CAMs?
- How do the auditor’s statements regarding CAMs compare with management’s disclosures regarding the same matters?

For more information about the PCAOB changes to the auditor’s report, see the following publications:

- The CAQ’s July 2018 publication.\(^8\)
- The CAQ’s December 2018 publication.\(^9\)

\(^8\) Critical Audit Matters: Key Concepts and FAQs for Audit Committees, Investors, and Other Users of Financial Statements.

\(^9\) Critical Audit Matters: Lessons Learned, Questions to Consider, and an Illustrative Example.
Appendix A — Titles of Standards and Other Literature

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

**AICPA Literature**

**Accounting and Valuation Guide**
*Assets Acquired to Be Used in Research and Development Activities*
*Valuation of Privately-Held-Company Equity Securities Issued as Compensation*

**Audit and Accounting Guide**
*Revenue Recognition*

**Issues Paper**
*Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories*

**Other**
*AICPA Technical Practice Aid, Section 2260.03, “Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit”*

**FASB Literature**

**ASC Topics**
*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 280, Segment Reporting*
*ASC 310, Receivables*
*ASC 320, Investments — Debt and Equity Securities*
*ASC 321, Investments — Equity Securities*
ASC 323, Investments — Equity Method and Joint Ventures
ASC 325, Investments — Other
ASC 326, Financial Instruments — Credit Losses
ASC 330, Inventory
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 450, Contingencies
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 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 840, Leases
ASC 842, Leases
ASC 845, Nonmonetary Transactions
ASC 850, Related Party Disclosures
ASC 855, Subsequent Events
Appendix A — Titles of Standards and Other Literature

ASC 915, Development Stage Entities

ASC 958, Not-for-Profit Entities

ASC 985, Software

**ASUs**

2010-20, Receivables (Topic 310): Disclosures About the Credit Quality of Financing Receivables and the Allowance for Credit Losses

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

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

2014-02, Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill — a consensus of the Private Company Council

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

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

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

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

2015-14, Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date


2016-02, Leases (Topic 842)

2016-04, Liabilities — Extinguishment of Liabilities (Subtopic 405-20): Recognition of Breakage for Certain Prepaid Store-Valued Products — a consensus of the FASB Emerging Issues Task Force

2016-08, Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)

2016-09, Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting

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

2016-11, Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting

2016-12, Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients
2016-13, Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments


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

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


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

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

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

2017-05, Other Income — Gains and Losses From the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets

2017-07, Compensation — Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost

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

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

2017-13, Revenue Recognition (Topic 605), Revenue From Contracts With Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Recission of Prior SEC Staff Announcements and Observer Comments (SEC Update)

2017-14, Income Statement — Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue From Contracts With Customers (Topic 606) (SEC Update)

2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842


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

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

2018-10, Codification Improvements to Topic 842, Leases

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


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

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

Concepts Statements
No. 5, Recognition and Measurement in Financial Statements of Business Enterprises
No. 6, Elements of Financial Statements
No. 8, Conceptual Framework for Financial Reporting — Chapter 1, The Objective of General Purpose Financial Reporting, and Chapter 3, Qualitative Characteristics of Useful Financial Information

Proposed ASUs
No. 2015-310, Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material
No. 2015-340, Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance
No. 2017-200, Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)
No. 2017-210, Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory
No. 2017-280, Consolidation (Topic 812): Reorganization
No. 2018-300, Codification Improvements — Financial Instruments
No. 2019-100, Targeted Transition Relief for Topic 326, Financial Instruments — Credit Losses

Other FASB Proposal

International Standards
IFRS 3, Business Combinations
IFRS 11, Joint Arrangements
IFRS 15, Revenue From Contracts With Customers
IFRS 16, Leases
IAS 10, Events After the Reporting Period
IAS 20, Accounting for Government Grants and Disclosure of Government Assistance
IRC
Section 78, “Gross Up for Deemed Paid Foreign Tax Credit”
Section 163(j), “Interest; Limitation on Business Interest”
Section 199, “Income Attributable to Domestic Production Activities”
Section 383, “Special Limitations on Certain Excess Credits, etc.”
Section 409A “Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans”
Section 422, “Incentive Stock Options”
Section 423, “Employee Stock Purchase Plans”
Section 965, “Treatment of Deferred Foreign Income Upon Transition to Participation Exemption System of Taxation”
Section 4191, “Medical Devices”

PCAOB Literature

SEC Literature
FRM
Topic 1, “Registrant’s Financial Information”
Topic 2, “Other Financial Statements Required”
Topic 3, “Pro Forma Financial Information”
Topic 7, “Related Party Matters”
Topic 9, “Management’s Discussion and Analysis of Financial Position and Results of Operations (MD&A)”
Topic 10, “Emerging Growth Companies”

Interpretive Release
33-10403, Updates to Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile

Regulation S-K
Item 103, “Business; Legal Proceedings”
**Regulation S-X**

Rule 1-02(w), “Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary”

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

Rule 3-09, “Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”

Rule 3-14, “Special Instructions for Real Estate Operations to Be Acquired”

Rule 4-08(g), “General Notes to Financial Statements: Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”

Rule 4-08(h), “General Notes to Financial Statements: Income Tax Expense”

Article 11, “Pro Forma Financial Information”

Rule 11-01 “Presentation Requirements”

**SAB Topics**

SAB Topic 1.M, “Financial Statements; Materiality”

SAB Topic 5.Y, “Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies”

SAB Topic 11.A, “Miscellaneous Disclosure; Operating-Differential Subsidies”

SAB Topic 13, “Revenue Recognition”

SAB Topic 14.B, “Share-Based Payment; Transition From Nonpublic to Public Entity Status”

SAB Topic 14.D.1, “Certain Assumptions Used in Valuation Methods; Expected Volatility”


SAB 116, “Staff Accounting Bulletin No. 116”

**Superseded Literature**

**EITF Issues**

Issue 00-21, “Revenue Arrangements With Multiple Deliverables”

Issue 01-8, “Determining Whether an Arrangement Contains a Lease”

Issue 01-9, “Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor’s Products)”

Issue 08-6, “Equity Method Investment Accounting Considerations”

Issue 09-2, “Research and Development Assets Acquired in an Asset Acquisition”

Issue 09-4, “Seller Accounting for Contingent Consideration”
FASB Interpretations
No. 48, Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109

FASB Statements
No. 5, Accounting for Contingencies
No. 123(R), Share-Based Payment
No. 141(R), Business Combinations
No. 160, Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51
## Appendix B — Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO</td>
<td>accumulated benefit obligation</td>
</tr>
<tr>
<td>AFS</td>
<td>available for sale</td>
</tr>
<tr>
<td>AICPA</td>
<td>American Institute of Certified Public Accountants</td>
</tr>
<tr>
<td>AMT</td>
<td>alternative minimum tax</td>
</tr>
<tr>
<td>AOCI</td>
<td>accumulated other comprehensive income</td>
</tr>
<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
</tr>
<tr>
<td>APIC</td>
<td>additional paid-in capital</td>
</tr>
<tr>
<td>ASC</td>
<td>FASB Accounting Standards Codification</td>
</tr>
<tr>
<td>ASR</td>
<td>accelerated share repurchase</td>
</tr>
<tr>
<td>ASU</td>
<td>FASB Accounting Standards Update</td>
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<tr>
<td>BCF</td>
<td>beneficial conversion feature</td>
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<tr>
<td>BEAT</td>
<td>base erosion anti-abuse tax</td>
</tr>
<tr>
<td>BEMTA</td>
<td>base erosion minimum tax amount</td>
</tr>
<tr>
<td>BOLI</td>
<td>bank-owned life insurance</td>
</tr>
<tr>
<td>BPD</td>
<td>branded prescription drug</td>
</tr>
<tr>
<td>CAM</td>
<td>critical audit matter</td>
</tr>
<tr>
<td>CAQ</td>
<td>Center for Audit Quality</td>
</tr>
<tr>
<td>CDO</td>
<td>chief digital officer</td>
</tr>
<tr>
<td>CECL</td>
<td>current expected credit loss</td>
</tr>
<tr>
<td>CFC</td>
<td>controlled foreign corporation</td>
</tr>
<tr>
<td>CMO</td>
<td>contract manufacturing organization</td>
</tr>
<tr>
<td>CODM</td>
<td>chief operating decision maker</td>
</tr>
<tr>
<td>COLI</td>
<td>corporate-owned life insurance</td>
</tr>
<tr>
<td>CRO</td>
<td>contract research organization</td>
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<tr>
<td>CTA</td>
<td>cumulative translation adjustment</td>
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</table>

<table>
<thead>
<tr>
<th>Abbreviation</th>
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</thead>
<tbody>
<tr>
<td>DTA</td>
<td>deferred tax asset</td>
</tr>
<tr>
<td>DTL</td>
<td>deferred tax liability</td>
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<tr>
<td>E&amp;P</td>
<td>earnings and profits</td>
</tr>
<tr>
<td>EBITDA</td>
<td>earnings before interest, taxes, depreciation, and amortization</td>
</tr>
<tr>
<td>EDGAR</td>
<td>SEC electronic data gathering, analysis, and retrieval system</td>
</tr>
<tr>
<td>EGC</td>
<td>emerging growth company</td>
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<tr>
<td>EITF</td>
<td>Emerging Issues Task Force</td>
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<tr>
<td>ESPP</td>
<td>employee stock purchase plan</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>FAQ</td>
<td>frequently asked question</td>
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<tr>
<td>FASB</td>
<td>Financial Accounting Standards Board</td>
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<tr>
<td>FAST Act</td>
<td>Fixing America’s Surface Transportation Act</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FDII</td>
<td>foreign derived intangible income</td>
</tr>
<tr>
<td>FIFO</td>
<td>first in, first out</td>
</tr>
<tr>
<td>FOB</td>
<td>free on board</td>
</tr>
<tr>
<td>FRM</td>
<td>SEC Division of Corporation Finance Financial Reporting Manual</td>
</tr>
<tr>
<td>GAAP</td>
<td>generally accepted accounting principles</td>
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<tr>
<td>GILTI</td>
<td>global intangible low-taxed income</td>
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<tr>
<td>GPO</td>
<td>group purchasing organization</td>
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<tr>
<td>IAS</td>
<td>International Accounting Standard</td>
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<tr>
<td>IASB</td>
<td>International Accounting Standards Board</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>IFRS</td>
<td>International Financial Reporting Standard</td>
</tr>
<tr>
<td>IIR</td>
<td>investigator-initiated research</td>
</tr>
<tr>
<td>IP</td>
<td>intellectual property</td>
</tr>
<tr>
<td>IPO</td>
<td>initial public offering</td>
</tr>
<tr>
<td>IPR&amp;D</td>
<td>in-process research and development</td>
</tr>
<tr>
<td>IRC</td>
<td>Internal Revenue Code</td>
</tr>
<tr>
<td>IRS</td>
<td>Internal Revenue Service</td>
</tr>
<tr>
<td>ISO</td>
<td>incentive stock option</td>
</tr>
<tr>
<td>IT</td>
<td>information technology</td>
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<tr>
<td>JOBS Act</td>
<td>Jumpstart Our Business Startups Act</td>
</tr>
<tr>
<td>LIFO</td>
<td>last in, first out</td>
</tr>
<tr>
<td>LLC</td>
<td>limited liability company</td>
</tr>
<tr>
<td>LP</td>
<td>limited partnership</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>merger and acquisition</td>
</tr>
<tr>
<td>MD&amp;A</td>
<td>Management's Discussion &amp; Analysis</td>
</tr>
<tr>
<td>MDET</td>
<td>medical device excise tax</td>
</tr>
<tr>
<td>MSL</td>
<td>medical science liaison</td>
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<tr>
<td>NFP</td>
<td>not-for-profit entity</td>
</tr>
<tr>
<td>NOL</td>
<td>net operating loss</td>
</tr>
<tr>
<td>NQSO</td>
<td>non-qualified stock option</td>
</tr>
<tr>
<td>NSO</td>
<td>nonstatutory option</td>
</tr>
<tr>
<td>OCI</td>
<td>other comprehensive income</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OEM</td>
<td>original equipment manufacturer</td>
</tr>
<tr>
<td>PBE</td>
<td>public business entity</td>
</tr>
<tr>
<td>PBO</td>
<td>projected benefit obligation</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>PCAOB</td>
<td>Public Company Accounting Oversight Board</td>
</tr>
<tr>
<td>PCC</td>
<td>Private Company Council</td>
</tr>
<tr>
<td>PCD asset</td>
<td>purchased financial asset with credit deterioration</td>
</tr>
<tr>
<td>PP&amp;E</td>
<td>property, plant, and equipment</td>
</tr>
<tr>
<td>PRV</td>
<td>priority review voucher</td>
</tr>
<tr>
<td>PTRS</td>
<td>probability of technical and regulatory success</td>
</tr>
<tr>
<td>Q&amp;A</td>
<td>question and answer</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>research and development</td>
</tr>
<tr>
<td>R&amp;E</td>
<td>research and experimentation</td>
</tr>
<tr>
<td>REMS</td>
<td>risk evaluation and mitigation strategy</td>
</tr>
<tr>
<td>ROI</td>
<td>return on investment</td>
</tr>
<tr>
<td>ROU</td>
<td>right of use</td>
</tr>
<tr>
<td>SAB</td>
<td>Staff Accounting Bulletin</td>
</tr>
<tr>
<td>SAC</td>
<td>subjective acceleration clause</td>
</tr>
<tr>
<td>SEC</td>
<td>Securities and Exchange Commission</td>
</tr>
<tr>
<td>SFC</td>
<td>specified foreign corporation</td>
</tr>
<tr>
<td>SIFMA</td>
<td>Securities Industry and Financial Markets Association</td>
</tr>
<tr>
<td>S&amp;P 500</td>
<td>Standard &amp; Poor's 500 Index</td>
</tr>
<tr>
<td>TD</td>
<td>Treasury Decision</td>
</tr>
<tr>
<td>TPA</td>
<td>AICPA Technical Practice Aid</td>
</tr>
<tr>
<td>TRG</td>
<td>transition resource group</td>
</tr>
<tr>
<td>UTB</td>
<td>unrecognized tax benefit</td>
</tr>
<tr>
<td>VIE</td>
<td>variable interest entity</td>
</tr>
<tr>
<td>VWAP</td>
<td>volume-weighted average daily market price</td>
</tr>
</tbody>
</table>