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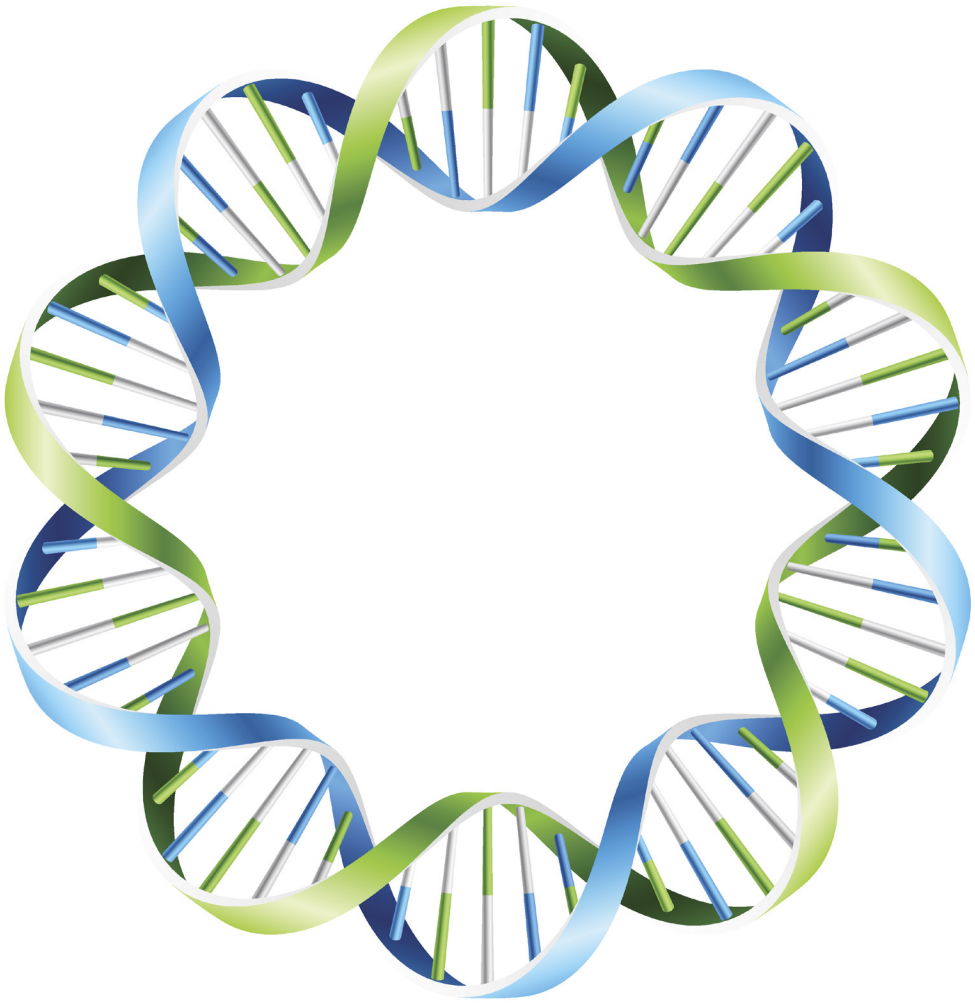

# Life Sciences

## Accounting and Financial Reporting Update — Interpretive Guidance on Research and Development

March 2019

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# Preface

March 2019

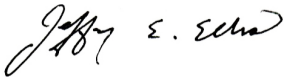
To our clients, colleagues, and other friends:

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. The full life sciences accounting and financial reporting update, our 10th edition, 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, it 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.

Sincerely,



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# Contents

# 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:

a. The entity guarantees, or has a contractual commitment that assures, repayment of the funds provided by the other parties regardless of the outcome of the research and development.

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

c. The other parties automatically will receive debt or equity securities of the entity upon termination or completion of the research and development regardless of the outcome.

Even in the absence of an explicit requirement for repayment, there may be other circumstances in which the entity will most likely bear the risk associated with the failure of the R&D activities. ASC 730-20-25-5 states 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:

a. The entity has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development.

b. The entity would suffer a severe economic penalty if it failed to repay any of the funds provided to it regardless of the outcome of the research and development. . . .

c. A significant related party relationship between the entity and the parties funding the research and development exists at the time the entity enters into the arrangement.

d. The entity has essentially completed the project before entering into the arrangement.

### 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:

**ASC 730-10 — Glossary**

**Research and Development**

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

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

ASC 730-10-25-2 explains the elements of costs to be identified with R&D activities:

**ASC 730-10**

**25-2** Elements of costs shall be identified with research and development activities as follows . . . :

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 the costs are incurred. . . .

b. Personnel. Salaries, wages, and other related costs of personnel engaged in research and development activities shall be included in research and development costs.

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 the costs are incurred.

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.

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.

## 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:

**ASC 730-10**

***Examples of Activities Typically Included in Research and Development***

**55-1** 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]):

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

***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:

| Branded Product | Generic Product | Medical Device |
|---|---|---|
| A new drug application has been submitted to the FDA for review, and phase III clinical trials have been completed. | An abbreviated new drug application has been submitted to and accepted by the FDA for review. | A 510(k) premarket approval application has been submitted to and accepted by the FDA for review. |

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*

**Example of an SEC Comment**

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:

- [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;
- [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;
- [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
- [T]he risks and uncertainties surrounding market acceptance of the product once approved and how this will affect the realization of the asset.

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[1] or rare pediatric[2] 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.

[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.

# 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*

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*

2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*

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

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*

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

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*

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

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 Rescission 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*

2018-02, *Income Statement — Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects From Accumulated Other Comprehensive Income*

2018-03, *Technical Corrections and Improvements to Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

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*

2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*

2018-14, *Compensation — Retirement Benefits — Defined Benefit Plans — General (Subtopic 715-20): Disclosure Framework — Changes to the Disclosure Requirements for Defined Benefit Plans*

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. 2016-270, *Income Taxes (Topic 740) Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes*

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

Proposed Concepts Statement 2014-200, *Conceptual Framework for Financial Reporting: Chapter 8: Notes to Financial Statements*

## 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

Release No. 2017-001, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion and Related Amendments to PCAOB Standards*

## 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 Topic 14.D.2, "Certain Assumptions Used in Valuation Methods; Expected Term"

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

| Abbreviation | Description |
|---|---|
| **ABO** | accumulated benefit obligation |
| **AFS** | available for sale |
| **AICPA** | American Institute of Certified Public Accountants |
| **AMT** | alternative minimum tax |
| **AOCI** | accumulated other comprehensive income |
| **API** | active pharmaceutical ingredient |
| **APIC** | additional paid-in capital |
| **ASC** | FASB Accounting Standards Codification |
| **ASR** | accelerated share repurchase |
| **ASU** | FASB Accounting Standards Update |
| **BCF** | beneficial conversion feature |
| **BEAT** | base erosion anti-abuse tax |
| **BEMTA** | base erosion minimum tax amount |
| **BOLI** | bank-owned life insurance |
| **BPD** | branded prescription drug |
| **CAM** | critical audit matter |
| **CAQ** | Center for Audit Quality |
| **CDO** | chief digital officer |
| **CECL** | current expected credit loss |
| **CFC** | controlled foreign corporation |
| **CMO** | contract manufacturing organization |
| **CODM** | chief operating decision maker |
| **COLI** | corporate-owned life insurance |
| **CRO** | contract research organization |
| **CTA** | cumulative translation adjustment |

| Abbreviation | Description |
|---|---|
| **DTA** | deferred tax asset |
| **DTL** | deferred tax liability |
| **E&P** | earnings and profits |
| **EBITDA** | earnings before interest, taxes, depreciation, and amortization |
| **EDGAR** | SEC electronic data gathering, analysis, and retrieval system |
| **EGC** | emerging growth company |
| **EITF** | Emerging Issues Task Force |
| **ESPP** | employee stock purchase plan |
| **EU** | European Union |
| **FAQ** | frequently asked question |
| **FASB** | Financial Accounting Standards Board |
| **FAST Act** | Fixing America's Surface Transportation Act |
| **FDA** | Food and Drug Administration |
| **FDII** | foreign derived intangible income |
| **FIFO** | first in, first out |
| **FOB** | free on board |
| **FRM** | SEC Division of Corporation Finance Financial Reporting Manual |
| **GAAP** | generally accepted accounting principles |
| **GILTI** | global intangible low-taxed income |
| **GPO** | group purchasing organization |
| **IAS** | International Accounting Standard |
| **IASB** | International Accounting Standards Board |

| Abbreviation | Description |
|---|---|
| **IFRS** | International Financial Reporting Standard |
| **IIR** | investigator-initiated research |
| **IP** | intellectual property |
| **IPO** | initial public offering |
| **IPR&D** | in-process research and development |
| **IRC** | Internal Revenue Code |
| **IRS** | Internal Revenue Service |
| **ISO** | incentive stock option |
| **IT** | information technology |
| **JOBS Act** | Jumpstart Our Business Startups Act |
| **LIFO** | last in, first out |
| **LLC** | limited liability company |
| **LP** | limited partnership |
| **M&A** | merger and acquisition |
| **MD&A** | Management's Discussion & Analysis |
| **MDET** | medical device excise tax |
| **MSL** | medical science liaison |
| **NFP** | not-for-profit entity |
| **NOL** | net operating loss |
| **NQSO** | non-qualified stock option |
| **NSO** | nonstatutory option |
| **OCI** | other comprehensive income |
| **OECD** | Organisation for Economic Co-operation and Development |
| **OEM** | original equipment manufacturer |
| **PBE** | public business entity |
| **PBO** | projected benefit obligation |

| Abbreviation | Description |
|---|---|
| **PCAOB** | Public Company Accounting Oversight Board |
| **PCC** | Private Company Council |
| **PCD asset** | purchased financial asset with credit deterioration |
| **PP&E** | property, plant, and equipment |
| **PRV** | priority review voucher |
| **PTRS** | probability of technical and regulatory success |
| **Q&A** | question and answer |
| **R&D** | research and development |
| **R&E** | research and experimentation |
| **REMS** | risk evaluation and mitigation strategy |
| **ROI** | return on investment |
| **ROU** | right of use |
| **SAB** | Staff Accounting Bulletin |
| **SAC** | subjective acceleration clause |
| **SEC** | Securities and Exchange Commission |
| **SFC** | specified foreign corporation |
| **SIFMA** | Securities Industry and Financial Markets Association |
| **S&P 500** | Standard & Poor's 500 Index |
| **TD** | Treasury Decision |
| **TPA** | AICPA Technical Practice Aid |
| **TRG** | transition resource group |
| **UTB** | unrecognized tax benefit |
| **VIE** | variable interest entity |
| **VWAP** | volume-weighted average daily market price |