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Life Sciences Industry Accounting Guide

Research and Development

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Preface

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

Finance and accounting professionals in the life sciences industry face complex issues and must exercise significant judgment in applying existing rules to matters such as research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The 2025 edition of Deloitte's *Life Sciences Industry Accounting Guide* (the "Guide") addresses these and other relevant topics affecting the industry this year. It includes interpretive guidance, illustrative examples, recent standard-setting and rulemaking developments (through March 7, 2025), and key differences between U.S. GAAP and IFRS® Accounting Standards. Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used. Key changes made to this Guide since publication of the 2024 edition are summarized in Appendix D.

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

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Chapter 2 — Research and Development

2.1 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 preclinical and clinical-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 expenses 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 this chapter, 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, including considerations related to accounting for prelaunch inventory.

2.2 Industry Issues

2.2.1 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 or compounds 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.

Life sciences companies may consider funding arrangements to help offset some of the costs associated with an R&D program. To determine the appropriate accounting treatment, entities 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:

ASC 815-10

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

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

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

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

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]

Connecting the Dots

R&D funding arrangements may include multiple payment provisions to the investor such as a payment upon regulatory approval of the compound that was subject to the R&D funding, as well as sales-based royalty payments from commercialization of the associated drug that received regulatory approval. When performing a derivative accounting assessment under ASC 815 in such cases, an entity will need to determine whether the payment provisions in the arrangement should be accounted for as a single unit of account or as multiple units of account. In situations in which the payment provisions should be accounted for as multiple units of account, each unit of account is individually assessed to determine whether it should be accounted for as a derivative. In situations in which the payment provisions should be accounted for as a single unit of account, the combined unit of account is assessed to determine whether it should be accounted for as a derivative. Such analysis becomes complex when certain payment provisions (underlyings) contained in the combined unit of account would have otherwise met one or more of the scope exceptions to the derivative accounting guidance in ASC 815 had they each been accounted for as a stand-alone unit of account (e.g., sales-based royalty) while other payment provisions would not have otherwise met any of those scope exceptions (e.g., payment based on regulatory approval). Regarding such a scenario, ASC 815-10-15-60 notes the following:

> If a contract has more than one underlying and some, but not all, of them qualify for one of the scope exceptions in the preceding paragraph, the application of this Subtopic to that contract depends on its predominant characteristics. That is, the contract is subject to the requirements of this Subtopic if all of its underlyings, considered in combination, behave in a manner that is highly correlated with the behavior of any of the component variables that do not qualify for a scope exception.

The determination of whether the multiple payment provisions (underlyings) considered together behave in a manner that is highly correlated with a component variable that does not qualify for a scope exception to the derivative accounting guidance can be challenging in practice and is likely to require both a qualitative and a quantitative assessment. Accordingly, entities are encouraged to consult with their accounting advisers.

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, in part, 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. 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. For further discussion of this guidance, see Section 7.2 of Deloitte's Roadmap *Issuer's Accounting for Debt*.

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 and safety 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. 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 ordinary activities in determining the appropriate income statement classification. If an entity's arrangement is consistent with the entity's ordinary activities (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 ordinary activities, 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, in part, 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.

Changing Lanes

In July 2024, the FASB issued a proposed ASU that would refine the scope of the guidance on derivatives in ASC 815 to exclude certain "contracts with underlyings based on operations or activities specific to one of the parties to the contract." Contracts that may qualify for this exception would include those in which the underlying is a business operation or an event such as obtaining regulatory approval or achieving specific business milestones. These types of underlyings may be common in R&D funding arrangements. The proposal would also change how the "predominant characteristics" of a contract are assessed when a contract has multiple underlyings, some of which qualify for scope exceptions and some of which do not.

For more information, see Deloitte's August 2, 2024, *Heads Up*.

2.2.1.1 R&D Funding Arrangements Involving New Legal Entities

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 life sciences company may be involved through participation on a committee (e.g., steering committee) or by performing R&D services through an outsourcing arrangement. The life sciences 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 life sciences 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 of any of the following:

- The equity investors with equity at risk are "capped" on receipt of the expected residual returns as a result of the R&D legal entity's arrangements with other variable interest holders. For example, a life sciences company's right or option to reacquire the rights to a compound effectively limits the returns that the equity investors can receive in such a way that the equity investors do not participate significantly in the profits.
- The R&D legal entity does not have sufficient equity to finance its operations (i.e., it is not sufficiently capitalized through its equity investment at risk). This situation is common because R&D legal entities often require additional subordinated financial support as a means to finance their activities.
- The equity investors with equity at risk do not have the power to direct the activities of the R&D legal entity that most significantly affect the R&D legal entity's economic performance.

In these situations, the evaluation should include consideration of whether the life sciences 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 life sciences 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 life sciences 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 life sciences company controls and should consolidate the legal entity.

If a life sciences company concludes that consolidation of an R&D entity is required, the percentage of equity not owned by the life sciences 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.

2.2.2 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 or therapy. 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.

2.2.2.1 *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* 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 (1) is reasonably expected to be used only in a specific IPR&D project and (2) 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. Similarly, if a life sciences company acquires a comparator drug that will only be used in one of its ongoing clinical trials, the cost of the comparator drug should be expensed when incurred because the comparator drug has no alternative future use in other R&D projects.

Alternatively, if a life sciences company uses a debt facility to fund R&D activities whose costs are required to be expensed as incurred, the interest associated with that debt facility would not be capitalized since it does not meet the criteria in ASC 835-20-15-5, which states that interest should be capitalized for the following types of assets:

a. Assets that are constructed or otherwise produced for an entity's own use, including assets constructed or produced for the entity by others for which deposits or progress payments have been made.

b. Assets intended for sale or lease that are constructed or otherwise produced as discrete projects . . . .

c. Investments (equity, loans, and advances) accounted for by the equity method while the investee has activities in progress necessary to commence its planned principal operations provided that the investee's activities include the use of funds to acquire qualifying assets for its operations. The investor's investment in the investee, not the individual assets or projects of the investee, is the qualifying asset for purposes of interest capitalization.

2.2.2.2 Software Used for R&D Activities

ASC 730-10

25-4 Development of software to be used in research and development activities includes costs incurred by an entity in developing computer software internally for use in its research and development activities, are research and development costs and, therefore, shall be charged to expense when incurred. The alternative future use test does not apply to the internal development of computer software; paragraph 730-10-25-2(c) applies only to intangibles purchased from others. This includes costs incurred during all phases of software development because all of those costs are incurred in a research and development activity.

Life sciences entities may internally develop software to be used in R&D activities. Such costs are considered R&D costs and would be charged to expense as incurred. Alternatively, if a life sciences entity purchases software from others to be used in R&D, the entity would assess whether such software has an alternative future use (in R&D projects or otherwise) as prescribed by ASC 730-10-25-2(c) and, if so, would account for the software costs in accordance with ASC 350. Otherwise, the purchase of software from others with no alternative future use would be considered R&D costs and would be charged to expense as incurred.

Example 2-1

Entity A, a manufacturer of medical devices, is developing internal-use software for use in its R&D activities. The entity is focused on creating a software platform that will enhance its R&D operations and integrate various research tools, data management systems, and analytical capabilities to support its research efforts. The goal is to create a comprehensive solution that improves efficiency, data accuracy, and collaboration among research teams. Because A is developing the internal-use software to be used in R&D activities, the costs of the software would be considered R&D costs and would be expensed as incurred in accordance with ASC 730-10-25-4.

2.2.2.3 Costs Incurred to Hire R&D Personnel

Life sciences companies may incur expenses, such as headhunting fees or signing bonuses, when hiring R&D personnel for R&D activities. In accordance with ASC 730-10-25-1 and 25-2(b), the costs incurred in connection with other related costs of personnel engaged in 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 such costs.

2.2.2.4 Costs Incurred to Obtain Regulatory Approval of Equipment That Has an Alternative Future Use

Life sciences companies may incur costs associated with the regulatory approval of manufacturing equipment that has an alternative future use. An entity may be required to (1) produce multiple batches of a finished product to obtain regulatory approval or (2) incur external and internal direct costs to validate new equipment or a new facility's compliance with regulation. Validation typically includes steps necessary to demonstrate, prove, and document that the facility, equipment, or both are producing the product in accordance with the same specifications as those met by the product that was submitted and approved by the regulatory agency. These costs may include, but are not limited to, payroll and payroll-related costs, travel, supplies, consultant fees, documentation costs, quality assurance testing costs, raw material testing costs, and validation batches.

In assessing whether the costs associated with obtaining regulatory approval of the manufacturing equipment should be capitalized, an entity should consider analogizing to the guidance in ASC 835-20-05-1, which states, in part, that the "historical cost of acquiring an asset includes the costs necessarily incurred to bring it to the condition and location necessary for its intended use." Accordingly, if activities performed as part of the regulatory approval process (i.e., the production of multiple batches of a finished product or the validation of facilities and equipment) are required to bring manufacturing equipment to the condition necessary for its intended use, the associated costs may be capitalized. Abnormal costs incurred during the regulatory approval process, such as costs associated with rework, should be expensed as incurred since they do not represent costs that are "necessarily incurred to bring [the asset] to the condition and location necessary for its intended use."

See Section 2.2.3 for considerations related to the capitalization of prelaunch inventory, which could include batches of inventory produced during the validation process.

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

Life sciences companies frequently enter into contract research arrangements with third parties (i.e., CROs) 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 730-10-25-1 and 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 such costs. To properly expense the contract research costs under the arrangement, the entity may need to (1) obtain periodic progress reports from the vendors on the level of services provided to date for which the entity is contractually obligated to pay and (2) engage with its regulatory affairs and clinical development teams for help in understanding when those costs were incurred. 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. Instead, estimates are often based on contracted amounts adjusted for the percentage of work completed to date, which may be measured on the basis of patient enrollments, the number of clinical sites opened, the duration for which patients will be enrolled in the study, patient visits, or some other reasonable measure of progress.

2.2.2.6 Examples of Activities Commonly Included in, or Excluded From, R&D Activities

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.

For example, suppose that Company X is sued for patent infringement and is incurring legal costs to defend the patent. FASB Concepts Statement 8, Chapter 4, which supersedes FASB Concepts Statement 6, defines an asset as follows:

> Assets
>
> E16. An asset is a present right of an entity to an economic benefit.
>
> *Characteristics of Assets*
>
> E17. An asset has the following two essential characteristics:
>
> a. It is a present right.
>
> b. The right is to an economic benefit.

The combination of those two characteristics allows an entity to obtain the economic benefit and control others' access to the benefit. A present right of an entity to an economic benefit entitles the entity to the economic benefit and the ability to restrict others' access to the benefit to which the entity is entitled.

Paragraph E23 of FASB Concepts Statement 8, Chapter 4, further observes that "the right to use a patent" is an example of a present right to an economic benefit and therefore gives rise to an asset. Accordingly, if legal costs incurred in successfully defending a patent create a present right to an economic benefit, capitalization of patent defense costs would be appropriate. In such a case, we would expect an entity to have sufficient, compelling evidence to support that conclusion. However, we believe that it may be challenging for an entity to support a conclusion that the legal defense costs meet the definition of an asset; if so, such costs should be expensed as incurred. Note that legal costs related to an unsuccessful outcome should be expensed.

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.

2.2.2.7 Activities Excluded From the Scope of ASC 730

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.

2.2.2.8 Classifications Requiring Judgment

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 expenses. Costs associated with certain activities that might require further judgment for classification as R&D expenses 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 to key thought leaders, professional societies, and practitioners clinical and scientific data and clinical education 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.

2.2.2.9 SEC Comment Letter Themes Related to R&D and Cost Classification

Examples of SEC Comments

- We acknowledge your statement that you do not track all of [your] internal research and development expenses on a program-by-program basis. In future filings, please quantify your internal research and development costs separately from the external costs incurred, and provide a further breakdown for each category. For example, you could provide a breakdown of your internal costs by nature of the expense incurred, and could disclose a breakdown of your external costs for each ongoing major clinical trial, instead of, or in addition to a breakdown by program area. Explain to us and revise your disclosures to clarify how the cost sharing arrangements with your collaboration partners . . . are recorded and reported in your financial statements, or direct us to existing disclosure.
- Please tell us whether you track any component of your research and development expenses by drug candidate . . . . If so represent to us that you will revise your disclosure in future filings to disaggregate research and development expenses by drug candidate for each period presented. If not, tell us whether you can provide more granular information, perhaps by nature, such as manufacturing expenses, clinical trial costs, preclinical study expenses, etc. in order to provide more insight into your research and development activities. Otherwise tell us why you cannot provide such additional detail or why its disclosure is not warranted.
- You make several assertions regarding the safety and efficacy of certain of your product candidates. For example, in your discussion . . . regarding an ongoing Phase I/II study of [Candidate], you disclose that "the data demonstrated that [Candidate] continues to be safe and well-tolerated, with no new serious adverse events and no development of inhibitors." In addition, in your discussion . . . of your preclinical [X] program, you disclose that these preclinical studies "demonstrate that [Candidate] appears to be safe due to a lack of off-target activity." Safety and efficacy determinations are solely within the authority of the FDA (or applicable foreign regulator). Please revise your future filings to remove statements/inferences that your product candidates are safe and/or effective. You may provide the objective results of the clinical trial in relation to the stated end points and indicate whether the candidates were well tolerated.
- We note the significant increase in your research and development expenses in [the fiscal year] and that you have multiple programs/products in varying stages of development and clinical testing, and note that you expect your research and development expenses to increase. Please confirm that you will revise future filings to provide more details about your research and development expenses for each period presented, including but not limited to by product/program, internal versus external, as well as by the nature of the expenses. For example, in discussing the specific reasons for significant changes in research and development expenses, quantify the change by each product candidate for which significant investments were made during the periods. Refer to Item 303(b) of Regulation S-K. To the extent that you do not track expenses by product candidate, please disclose as such.
- Please provide us a breakdown of your research and development ("R&D") expenses incurred for each year presented by product candidate or project. To the extent that you do not track costs by project, please explain how your R&D costs are managed and how they are reported within the organization. To the extent that you can distinguish your R&D costs by discovery, preclinical and clinical development categories and/or therapeutic class or by the type of cost, please provide us with this information. Please also tell us your consideration of disclosing this information given that you consider research and development to be essential to your business.
- [Y]ou indicate that your external research and development costs include legal fees. Please tell us:
  - The nature of these legal fees;
  - The amount of legal fees included in research and development expenses in each of the last three fiscal years and the [first through third quarters of the current fiscal year]; and
  - How these legal fees meet the definition of either research or development in ASC 730-10-20 and your consideration of the guidance in ASC 730-10-55-2i.

Examples of SEC Comments (continued)

- Please disclose your accounting policies for research and development expenses and intellectual property intangible assets. With reference to the nature of the intellectual property rights acquired as disclosed . . . , please address how you determined there is an alternative future use for these assets, such that it was appropriate to capitalize the cost of these assets. Refer to ASC 730-10-25-2(c).

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. For more information about themes we have identified in our review of SEC comment letters issued to registrants in the life sciences industry, see Section 6.4 of Deloitte's Roadmap *SEC Comment Letter Considerations, Including Industry Insights*.

2.2.3 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 (NDA) has been submitted to the FDA for review, and phase III clinical trials have been completed.	An abbreviated new drug application (ANDA) 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, as previously noted, is defined in paragraphs E16 and E17 of FASB Concepts Statement 8, Chapter 4. Paragraph E17 states, in part:

> An asset has the following two essential characteristics:
>
> a. It is a present right.
>
> b. The right is to an economic benefit.

When a life sciences entity is evaluating whether prelaunch inventory (i.e., before regulatory approval) is a present right to an economic benefit and therefore meets the definition of an asset, the 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.

In addition, a life sciences company engaging in clinical trials may require manufactured products for patients enrolled in a trial. Such products may only be used to support the ongoing clinical trial and may include raw materials acquired for production. Management should evaluate whether raw materials acquired for production should be accounted for as inventory if they would have an alternative future use, as discussed in Section 2.2.2 (i.e., the raw materials could be used in the production of multiple drugs). The costs of materials acquired for a particular R&D project that have no alternative future use (e.g., in other R&D projects) and, therefore, no separate economic value are R&D costs at the time the costs are incurred. Further, the costs of raw materials consumed in R&D activities are R&D costs.

2.2.3.1 SEC Comment Letter Themes Related to Capitalization of Prelaunch Inventory

Example of an SEC Comment

You disclose that inventory costs incurred prior to receipt of regulatory approval are charged to research and development costs when incurred. You also disclose . . . that inventories on your period end balance sheets are comprised primarily of raw materials purchased subsequent to FDA approval of [Product A]. Please tell us the following:

- The dollar value of pre-approval inventory costs charged to research and development costs and the calendar years in which those costs were expensed.
- An estimate of what cost of sales as a percentage of product revenue, net would have been for each quarter from the third quarter of [fiscal year 1] through the third quarter of [fiscal year 2] if you had not charged pre-approval inventory costs to research and development expenses.
- The estimated amount of future product revenue, net from sales of the zero-cost/low-cost inventory (i.e. inventory that excludes costs charged to expense prior to regulatory approval) on hand at September 30, [fiscal year 2] and the expected period of time over which it will be sold.

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 E16 of FASB Concepts Statement 8, Chapter 4.

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.

2.2.4 Nonrefundable Advance Payments

Life sciences entities may 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 730-20-25-13, ASC 730-20-25-14, and ASC 730-20-35-1 provide 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 (1) deferred and capitalized and (2) subsequently "recognized as an expense as the related goods are delivered or the related services are 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).

2.2.4.1 Donations to Fund R&D

A life sciences entity may commit to making a donation to an NFP (e.g., a community organization, college or university, museum, or other organization listed in ASC 958-10-15-3) to fund research activities of the NFP. In such a situation, the life sciences entity should consider whether a contribution has been made and, if so, when the contribution should be recognized. In the ASC 720-25 glossary, a contribution is defined, in part, as an "**unconditional transfer of cash or other assets, as well as unconditional promises to give, to an entity** . . . in a voluntary nonreciprocal transfer by another entity acting other than as an owner" (emphasis added). With respect to recognition, ASC 720-25-25-1 states, in part, that "[c]ontributions made shall be recognized as expenses in the period made," and "unconditional promises to give cash are recognized as payables and contribution expenses." Further, ASC 720-25-30-1 requires contributions made to "be measured at the fair values of the assets given or, if made in the form of a settlement or cancellation of a donee's liabilities, at the fair value of the liabilities cancelled."

2.2.5 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 Section 7.2.1 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.

Connecting the Dots

In Australia, certain companies are eligible for a tax offset under the Australian government's R&D Tax Incentive program, a strategic initiative designed to encourage and support businesses engaged in R&D activities. The determination of whether the R&D tax offset is refundable or nonrefundable and the applicable rate depend on the aggregated turnover of the R&D entity.

To qualify for the tax offset, companies incorporated in Australia must incur eligible expenses exceeding AUD 20,000 per financial year and engage in at least one eligible core R&D activity. The government program offers eligible companies a refundable tax offset of either 43.5 percent or 48.5 percent of R&D expenses if their aggregated turnover is less than AUD 20 million per financial year and they have sufficient tax losses.

For companies with an aggregated turnover of at least AUD 20 million per financial year, a nonrefundable tax offset on eligible expenses is available. This provides a reduction in tax liability equivalent to at least 8.5 percent for eligible R&D expenses. A premium of 16.5 percent is available on R&D expenditure exceeding a 2 percent R&D intensity threshold. The intensity is based on the proportion of R&D expenditure to total expenses.

Companies considering tax planning strategies associated with Australia's R&D Tax Incentive program are encouraged to consult with their accounting and tax advisers.

2.2.6 FDA Priority Review Vouchers

Sections 524 and 529 of the Federal Food, Drug, and Cosmetic Act authorize 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, respectively. 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.

[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.

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 provide for a present right to an economic benefit (i.e., meet the definition of an asset). Companies should carefully consider management's intent and whether a present right to an economic benefit exists when determining how to account for the acquisition of PRVs.

Similarly, life sciences companies will need to consider how to account for the sale of PRVs. Specifically, a life sciences company that sells PRVs will have to assess whether the PRVs are outputs of the company's ordinary activities to determine whether to account for the sale under ASC 606 or under ASC 610-20. We recommend that life sciences companies work with their accounting advisers and external auditors on the appropriate approach and accounting treatment for this type of transaction.

Appendix B — Titles of Standards and Other Literature

AICPA Literature

Accounting and Valuation Guides

Assets Acquired to Be Used in Research and Development Activities

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

Clarified Statements on Auditing Standards

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

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

FASB Literature

ASC Topics

ASC 105, *Generally Accepted Accounting Principles*

ASC 205, *Presentation of Financial Statements*

ASC 210, *Balance Sheet*

ASC 220, *Income Statement — Reporting Comprehensive Income*

ASC 230, *Statement of Cash Flows*

ASC 235, *Notes to Financial Statements*

ASC 250, *Accounting Changes and Error Corrections*

ASC 260, *Earnings per Share*

ASC 270, *Interim Reporting*

ASC 275, *Risks and Uncertainties*

ASC 280, *Segment Reporting*

ASC 310, *Receivables*

ASC 320, *Investments — Debt Securities*

ASC 321, *Investments — Equity Securities*

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

ASC 326, *Financial Instruments — Credit Losses*

ASC 330, *Inventory*

ASC 340, *Other Assets and Deferred Costs*

ASC 350, *Intangibles — Goodwill and Other*

ASC 360, *Property, Plant, and Equipment*

ASC 405, *Liabilities*

ASC 410, *Asset Retirement and Environmental Obligations*

ASC 420, *Exit or Disposal Cost Obligations*

ASC 440, *Commitments*

ASC 450, *Contingencies*

ASC 460, *Guarantees*

ASC 470, *Debt*

ASC 480, *Distinguishing Liabilities From Equity*

ASC 505, *Equity*

ASC 605, *Revenue Recognition*

ASC 606, *Revenue From Contracts With Customers*

ASC 610, *Other Income*

ASC 705, *Cost of Sales and Services*

ASC 710, *Compensation — General*

ASC 712, *Compensation — Nonretirement Postemployment Benefits*

ASC 715, *Compensation — Retirement Benefits*

ASC 718, *Compensation — Stock Compensation*

ASC 720, *Other Expenses*

ASC 730, *Research and Development*

ASC 740, *Income Taxes*

ASC 805, *Business Combinations*

ASC 808, *Collaborative Arrangements*

ASC 810, *Consolidation*

ASC 815, *Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 830, *Foreign Currency Matters*

ASC 832, *Government Assistance*

ASC 835, *Interest*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 845, *Nonmonetary Transactions*

ASC 848, *Reference Rate Reform*

ASC 852, *Reorganizations*

ASC 855, *Subsequent Events*

ASC 860, *Transfers and Servicing*

ASC 905, *Agriculture*

ASC 915, *Development Stage Entities*

ASC 930, *Extractive Activities — Mining*

ASC 944, *Financial Services — Insurance*

ASC 946, *Financial Services — Investment Companies*

ASC 954, *Health Care Entities*

ASC 958, *Not-for-Profit Entities*

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

ASC 970, *Real Estate — General*

ASC 985, *Software*

ASUs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Appendix C — Abbreviations

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

Abbreviation	Description
CECL	current expected credit loss
CFC	controlled foreign corporation
CIMA	Chartered Institute of Management Accountants
CMO	contract manufacturing organization
CODM	chief operating decision maker
CPU	central processing unit
CRO	contract research organization
CSRD	Corporate Sustainability Reporting Directive
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
EC	European Commission
ED	exposure draft
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EFRAG	European Financial Reporting Advisory Group
EGC	emerging growth company
EITF	Emerging Issues Task Force
ELOC	equity line of credit
EPS	earnings per share
ESA	energy service agreement
ESG	environmental, social, and governance
ESPP	employee stock purchase plan
ESRS	European Sustainability Reporting Standards

Abbreviation	Description
E.U.	European Union
EUR	euros
Exchange Act	Securities Exchange Act of 1934
FAQ	frequently asked question
FASB	Financial Accounting Standards Board
FAST Act	Fixing America's Surface Transportation Act
FDA	U.S. Food and Drug Administration
FDII	foreign-derived intangible income
FOB	free on board
FPI	foreign private issuer
FRM	SEC Division of Corporation Finance Financial Reporting Manual
FVO	fair value option
FVTOCI	fair value through other comprehensive income
GAAP	generally accepted accounting principles
GDP	gross domestic product
GHG	greenhouse gas
GILTI	global intangible low-taxed income
GloBE	Global anti-Base Erosion
GPO	group purchasing organization
GPU	graphics processing unit
HAFWP	how and for what purpose
HFI	held for investment
HFS	held for sale
HVAC	heating, ventilation, and air conditioning
IAS	International Accounting Standard
IASB	International Accounting Standards Board
ICFR	internal control over financial reporting
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research

Abbreviation	Description
IOSCO	International Organization of Securities Commissions
IP	intellectual property
IPO	initial public offering
IPR&D	in-process research and development
IRA	Inflation Reduction Act of 2022
IRC	Internal Revenue Code
IRS	Internal Revenue Service
ISO	incentive stock option
ISSB	International Sustainability Standards Board
IT	information technology
ITC	invitation to comment
JOBS Act	Jumpstart Our Business Startups Act
LCD	liquid-crystal display
LIBOR	London Interbank Offered Rate
LIFO	last in, first out
LLM	large language model
M&A	merger and acquisition
MD&A	Management's Discussion & Analysis
MNE	multinational enterprise
MSL	medical science liaison
NDA	new drug application
NFP	not-for-profit (entity)
NFRD	Non-Financial Reporting Directive
NIH	National Institutes of Health
NLP	natural language processing
NOL	net operating loss
NOPA	notice of proposed adjustment
NQSO or **NSO**	nonqualified stock option
OCA	SEC Office of the Chief Accountant
OCI	other comprehensive income

Abbreviation	Description
OECD	Organisation for Economic Co-operation and Development
OEM	original equipment manufacturer
PBE	public business entity
PCAOB	Public Company Accounting Oversight Board
PCC	Private Company Council
PIPE	private investment in public equity
PP&E	property, plant, and equipment
PRV	priority review voucher
PTRS	probability of technical and regulatory success
Q&A	question and answer
QIP	qualified improvement property
R&D	research and development
R&E	research and experimental
RAM	random-access memory
REMS	risk evaluation and mitigation strategy
RIM	retail inventory method
ROU	right-of-use
SaaS	software as a service
SAB	SEC Staff Accounting Bulletin
SAFE	simple agreement for future equity
SEC	U.S. Securities and Exchange Commission

Abbreviation	Description
Securities Act	Securities Act of 1933
SEPA	standby equity purchase agreement
SG&A	selling, general, and administrative
SOX	Sarbanes-Oxley Act of 2002
SPAC	special-purpose acquisition company
SPPI	solely payments of principal and interest
SRC	smaller reporting company
S&P 500	Standard & Poor's 500 Index
TCFD	Task Force on Climate-related Financial Disclosures
TD	Treasury Decision
TDR	troubled debt restructuring
TRG	transition resource group
TSA	transition services agreement
USD	U.S. dollar(s)
UTB	unrecognized tax benefit
VCO	voluntary carbon offset
VIE	variable interest entity
VWAP	volume-weighted average daily market price
XBRL	eXtensible Business Reporting Language

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