



Life Sciences

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

March 2018

Research and Development

Introduction

New product development in the life sciences industry is 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 the Industry Issues section 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.

Industry Issues

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.



Considerations Relevant to Life Sciences Companies' Accounting for R&D Funding Arrangements

Question

What factors should life sciences companies that receive R&D funding consider when accounting for R&D funding arrangements?

Answer

To determine the appropriate accounting treatment, life sciences companies should consider, among other things, the risks associated with the R&D program being funded, as well as the deliverable(s) (i.e., license rights to IP subject to the R&D program) to be provided to the funding party. Such factors may inform the companies' decision about which accounting literature to consider, particularly if a conclusion is reached that the arrangement is a contract to perform services that should be accounted for in accordance with ASC 605 (or ASC 606 upon adoption of the new revenue standard).

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 not a “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 increasing the number of covered products; such circumstances must be carefully evaluated, and other factors (e.g., number of products, stage of development of each, payment mechanisms) would be important.
- *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, companies should assess whether sales-based royalties to be paid on overall product sales should be considered an unrelated revenue stream if the R&D funding arrangement was specific to certain indications and did not include R&D activities for all indications for which the respective compound is approved and marketed. Such evaluation is critical if the compound is already approved and marketed for certain indications.

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

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 605-45 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 the arrangement is consistent with the entity's central operations (i.e., the entity regularly performs research on behalf of others), 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, an 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. However, if the counterparty is only passively involved, classification as other income may be more appropriate.

R&D Funding Arrangements Involving New Legal Entities



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, many recent arrangements have included the formation of a new legal entity. Typically, the new legal entity is 100 percent owned by a financial investor, and the pharmaceutical company may be involved through participation on a committee (e.g., steering committee) or by performing R&D services through an outsourcing arrangement. The pharmaceutical company may also have the right or option to reacquire the rights to the compound(s) at a later date.

When an R&D arrangement involves the formation of a new legal entity, 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 the decisions of the financial investor(s) are passive or predetermined, or when the pharmaceutical company has a fixed-price call option to acquire the legal entity, since these types of circumstances could suggest that (1) the financial investors lack the characteristics of a controlling financial interest and (2) the pharmaceutical company controls and should consolidate the legal entity.

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

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 (as discussed above) and, if so, whether the reporting entity should consolidate the VIE. 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.



Whether R&D Arrangements 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 810-30-55.¹ 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.

¹ On September 20, 2017, the FASB issued for public comment [FASB Proposed Accounting Standards Update, Consolidation \(Topic 812\), Reorganization](#). Among other proposed amendments (see the [Consolidation](#) section below for further details), the proposed ASU would eliminate the R&D guidance provided in ASC 810-30 since user outreach has indicated that this guidance is not used in practice.

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.

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

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.

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. Q&A paragraph 2260.03 of *AICPA Technical Questions and Answers* 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 ASC 730-10-15-4(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 or 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.

SEC Comment Letter Themes Related to R&D Cost Classification

Examples of SEC Comments

- 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 of fiscal 2016 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.

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.
- 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.

SEC Comment Letter Themes Related to Capitalization of Prelaunch Inventory

Example of an SEC Comment

Please tell us the following information associated with the batches of inventory manufactured for sale but charged to research and development expense prior to the fourth quarter of 2016:

- The amount of costs associated with these batches of inventory that were charged to research and development expenses through [period-end].
- In terms of some measure of volume, the number of units or batches on hand at each [comparative period-end] for which you have zero or low cost ("zero-cost inventory").
- The impact on your historical results of operations for the first and second quarter of [the period] in terms of what cost of goods sold and negative gross profit would have been if you had not charged the direct and indirect costs to manufacture these batches to research and development expenses.
- The estimated selling value of and the estimated period to sell this zero-cost inventory at each [comparative period-end].
- If the estimated periods to sell this zero-cost inventory and the inventories recorded on your balance sheet are expected to exceed your estimated product sales for the next twelve months, tell us why you reflect none of your inventory on your [comparative period-end] balance sheets as non-current given your disclosed first-in, first-out basis of inventory accounting.
- If you expect a significant amount of inventory on hand and in the distribution channel at each of the [comparative period-ends] to be sold after one year from each of these dates, tell us the shelf life of [Product A] and why you believe you will be able to realize the capitalized inventory at each of these dates.
- If known, the estimated range of cost of goods sold as a percentage of revenue for the expected sales of inventory that you have capitalized; i.e., the normalized estimated range once you sell all your zero-cost inventory.

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.

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 that it 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, an entity is required to recognize and measure at fair value a liability for the costs of terminating

a 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 its fair value when the entity stops receiving future services.

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 the [Income Taxes](#) section of this publication 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.

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 tropical² or rare pediatric³ 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. 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.

² As defined in Section 524(a)(3) and (a)(4) of the Federal Food, Drug, and Cosmetic Act.

³ As defined in Section 529(a)(3) of the Federal Food, Drug, and Cosmetic Act.

Appendix A — Glossary 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*

AICPA Issues Paper, *Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories*

AICPA Technical Questions and Answers, Q&A paragraph 2260.03, "Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit"

FASB Accounting Standards Updates (ASUs)

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

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

ASU 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*

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

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 2017-09, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting*

ASU 2017-07, *Compensation — Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost*

ASU 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*

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

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

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

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

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

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

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

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

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

ASU 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*

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

ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*

ASU 2016-08, *Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)*

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

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

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

ASU 2015-14, *Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date*

ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis*

ASU 2015-01, *Income Statement — Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*

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

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

ASU 2014-02, *Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill* — a consensus of the Private Company Council

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 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 2010-20, *Receivables (Topic 310): Disclosures About the Credit Quality of Financing Receivables and the Allowance for Credit Losses*

ASU 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements* — a consensus of the FASB Emerging Issues Task Force

FASB Accounting Standards Codification (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 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 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 915, Development Stage Entities

ASC 958, Not-for-Profit Entities

ASC 985, Software

Proposed FASB Accounting Standards Updates (Proposed ASUs)

Proposed ASU 2018-200, *Leases (Topic 842): Targeted Improvements*

Proposed ASU 2017-310, *Technical Corrections and Improvements to Recently Issued Standards: I. Accounting Standards Update No. 2016-01, Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities and II. Accounting Standards Update No. 2016-02, Leases (Topic 842)*

FASB Proposed Accounting Standards Update 2017-280, *Consolidation (Topic 812): Reorganization*

FASB Proposed Accounting Standards Update 2017-240, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

Proposed ASU 2017-220, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*

Proposed ASU 2017-210, *Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory*

Proposed ASU 2017-200, *Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)*

Proposed ASU 2016-270, *Income Taxes (Topic 740) Disclosure Framework: Changes to the Disclosure Requirements for Income Taxes*

Proposed ASU 2015-340, *Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance*

Proposed ASU 2015-310, *Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material*

Other FASB Proposal

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

FASB Statements (Pre-Codification Literature)

Statement No. 167, *Amendments to FASB Interpretation No. 46(R)*

Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements* — an amendment of ARB No. 51

Statement No. 141(R), *Business Combinations*

FASB Interpretations (Pre-Codification Literature)

FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109

FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*

FASB Concepts Statements

No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*

No. 6, *Elements of Financial Statements*

EITF Issues (Pre-Codification Literature)

Issue 09-4, "Seller Accounting for Contingent Consideration"

Issue 08-1, "Revenue Arrangements With Multiple Deliverables"

Issue 04-5, "Determining Whether a General Partner, or the General Partners as a Group, Controls a Limited Partnership or Similar Entity When the Limited Partners Have Certain Rights"

Issue 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)"

Issue 01-8, "Determining Whether an Arrangement Contains a Lease"

Issue 00-21, "Revenue Arrangements With Multiple Deliverables"

PCAOB Auditing Standard

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 C&DI Topic

Non-GAAP Financial Measures

SEC 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*

SEC Regulation G

"Conditions for Use of Non-GAAP Financial Measures"

SEC Regulation S-K

Item 10(e), "General; Use of Non-GAAP Financial Measures in Commission Filings"

Item 103, "Business; Legal Proceedings."

SEC Regulation S-X

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"

SEC Staff Accounting Bulletins (SABs)

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 Subsidiaries"

SAB Topic 13, "Revenue Recognition"

SAB Topic 13.A.4, "Revenue Recognition; Selected Revenue Recognition Issues; Fixed or Determinable Sales Price"

SAB Topic 13.B, "Revenue Recognition; Disclosures"

SAB 116, "Staff Accounting Bulletin No. 116"

SAB 118, codified as SEC Staff Accounting Bulletin Topic 5.EE, "Miscellaneous Accounting; Income Tax Accounting Implications of the Tax Cuts and Jobs Act"

Internal Revenue Code (IRC)

IRC Section 78, "Gross Up for Deemed Paid Foreign Tax Credit"

IRC Section 163(j), "Interest; Limitation on Business Interest"

IRC Section 199, "Income Attributable to Domestic Production Activities"

IRC Section 383, "Special Limitations on Certain Excess Credits, Etc."

IRC Section 787, "Termination of Private Foundation Status"

IRC Section 965, "Treatment of Deferred Foreign Income Upon Transition to Participation Exemption System of Taxation"

IRC Section 4191, "Medical Devices"

International Standards

IFRS 16, *Leases*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 11, *Joint Arrangements*

IFRS 3, *Business Combinations*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*

Appendix B — Abbreviations

Abbreviation	Description	Abbreviation	Description
AFS	available for sale	E&P	earnings and profits
AICPA	American Institute of Certified Public Accountants	EPS	earnings per share
AMT	alternative minimum tax	EU	European Union
AOCI	accumulated other comprehensive income	FAQ	frequently asked question
API	active pharmaceutical ingredient	FASB	Financial Accounting Standards Board
APIC	additional paid-in capital	FDA	Food and Drug Administration
ASC	FASB Accounting Standards Codification	FDII	foreign derived intangible income
ASU	FASB Accounting Standards Update	FIFO	first in, first out
BCF	beneficial conversion feature	FIN	FASB Interpretation Number (superseded)
BEAT	base erosion anti-abuse tax	FOB	free on board
BEMTA	base erosion minimum tax amount	GAAP	generally accepted accounting principles
BPD	branded prescription drug	GILTI	global intangible low-taxed income
BOLI	bank-owned life insurance	GPO	group purchasing organization
CAM	critical audit matter	IAS	International Accounting Standard
C&DI	SEC Compliance and Disclosure Interpretation	IASB	International Accounting Standards Board
CECL	current expected credit loss	IFRS	International Financial Reporting Standard
CFC	controlled foreign corporation	IIR	investigator-initiated research
CODM	chief operating decision maker	IP	intellectual property
COLI	corporate-owned life insurance	IPO	initial public offering
CRO	contract research organization	IPR&D	in-process research and development
CTA	cumulative translation adjustment	IRC	Internal Revenue Code
DCPs	disclosure controls and procedures	IRS	Internal Revenue Service
DTA	deferred tax asset	IT	information technology
DTL	deferred tax liability	LIFO	last in, first out
EBITDA	earnings before interest, taxes, depreciation, and amortization	LLC	limited liability company
EITF	FASB Emerging Issues Task Force		

Abbreviation	Description
LP	limited partnership
M&A	merger and acquisition
MD&A	Management's Discussion and Analysis
MDET	medical device excise tax
MSL	medical science liaison
NFP	not-for-profit entity
NOL	net operating loss
OCI	other comprehensive income
OEM	original equipment manufacturer
OECD	Organisation for Economic Co-operation and Development
PBE	public business entity
PCAOB	Public Company Accounting Oversight Board
PCC	Private Company Council
PCD asset	purchased financial asset with credit deterioration
PRV	priority review voucher

Abbreviation	Description
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
ROU	right-of-use
SAB	SEC Staff Accounting Bulletin
SEC	Securities and Exchange Commission
SFC	specified foreign corporation
SIFMA	Securities Industry and Financial Markets Association
T.D.	Treasury Decision
TRG	transition resource group
UTB	unrecognized tax benefit
VIE	variable interest entity
WAC	wholesaler acquisition cost

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