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US GAAP – Issues and solutions for the pharmaceuticals and life science industries

2017 edition

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Foreword

The pharmaceutical and life sciences industry has been and continues to be shaped by government actions, regulatory and public scrutiny, and changes in the overall business environment. These changes have included income tax regulations impacting the strategy for mergers and acquisitions, numerous provisions of healthcare reform, innovation involving emerging technologies, the evolution of big data, and multiple changes to US generally accepted accounting principles (US GAAP).

The complete overhaul for recognizing revenue under both IFRS and US GAAP has required countless hours of preparation and promises to continue to require committed resources through adoption and beyond. Further, in recent years, companies from differing sectors have created unions with a target of continued innovation. Transactions, such as these, in combination with the changes to US GAAP create challenging situations for companies in the pharmaceutical and life sciences industry.

This publication highlights industry-specific factors to be considered and provides guidance on the most pertinent accounting solutions for the pharmaceutical and life sciences industry. Because each company deals with accounting issues in ways that should reflect the facts and circumstances of its particular situation, we cannot address every nuance in this publication. For example, creativity in licensing, manufacturing, and research and development arrangements lead to variations in contracts, corporate structures, and accounting requirements. Therefore, the solutions we present are meant to provide a framework for determining the appropriate accounting answer for general situations; however, individual fact patterns and structuring of arrangements may give rise to a different answer.

The contents of this publication are based on guidance that is effective or could be early adopted as of January 1, 2017, including ASC 606. In other solutions contained in the publication, the accounting guidance may be superseded as new guidance and interpretations emerge.

We hope you find this publication useful in addressing and understanding the accounting for certain transactions encountered in your business. Further, we hope that this publication will encourage consistent practices by pharmaceutical and life sciences companies in financial reporting under US GAAP. This consistency will be critical to the continued usefulness and transparency of pharmaceuticals and life sciences companies' financial statements.

PwC Pharmaceutical and Life Sciences Practice

We recommend that you reference the website <http://www.pwc.com/us/pharma> as your primary source for this publication and other thought leadership materials.



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*Capitalization and
impairment*

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1. Capitalization of internal development costs: timing – Scenario 1

Background



Company A is developing a vaccine for HIV that has successfully completed Phases I and II of testing. The drug is now in Phase III of testing. Management still has concerns about securing regulatory approval and has not started manufacturing or marketing the vaccine.

Relevant guidance



Research and development costs... shall be charged to expense when incurred [ASC 730-10-25-1].

How should management account for research and development costs incurred related to this project? ↓



Solution

Costs to perform research and development, including internal development costs, should be expensed as incurred.

2. Capitalization of internal development costs: timing – Scenario 2

Background



A pharmaceutical entity is developing a vaccine for HIV that has successfully completed Phases I and II of testing. The drug is now in the late stages of Phase III testing. It is structurally similar to drugs the entity has successfully developed in the past with very low levels of side effects, and management believes it will be favorably treated by the regulatory authority because it meets a currently unmet clinical need.

Relevant guidance



Research and development costs... shall be charged to expense when incurred [ASC 730-10-25-1].

Should management start capitalizing the development costs? ↓



Solution

No. Costs to perform research and development, including internal development costs, should be expensed as incurred, regardless of past history with similar drugs or regulatory approval expectations. Research and development costs should not be capitalized.

3. **Capitalization of internal development costs when regulatory approval has been obtained in a similar market**

Background



An entity has obtained regulatory approval for a new respiratory drug in Country A. It is now progressing through the additional development procedures necessary to gain approval in Country B.

Management believes that achieving regulatory approval in this secondary market is a formality. Mutual recognition treaties and past experience show that Country B's authorities rarely refuse approval for a new drug that has been approved in Country A.

Relevant guidance



Research and development costs... shall be charged to expense when incurred [ASC 730-10-25-1].

Should the development costs associated with the additional development procedures necessary to gain approval in Country B be capitalized? ↓



Solution

No. The development costs should be expensed as incurred, regardless of the probability of success and history.

4. Capitalization of development costs for generics

Background



An entity is developing a generic version of a painkiller that has been sold in the market by another company for many years. The technological feasibility of the drug has already been established because it is a generic version of a product that has already been approved, and its chemical equivalence has been demonstrated. The lawyers advising the entity do not anticipate that any significant difficulties will delay the process of obtaining commercial regulatory approval.

Relevant guidance



Research and development costs... shall be charged to expense when incurred [ASC 730-10-25-1].

Should management capitalize the development costs at this point? ↓



Solution

No. Research and development costs should be expensed as incurred.

5. *Development expenditure once capitalization criteria are met—Scenario 1*

Background



Company A has obtained regulatory approval for a new respiratory drug and is now incurring costs to educate its sales force and perform market research.

Relevant guidance



Expenses are outflows or other using up of assets or incurrences of liabilities (or a combination of both) from delivering or producing goods, rendering services, or carrying out other activities that constitute the entity's ongoing major or central operations [CON 6, par. 80].

Should Company A capitalize these costs? ↓



Solution

No. Company A should expense sales and marketing expenditures, such as training a sales force or performing market research, as incurred. This type of expenditure does not create, produce or prepare the asset for its intended use.

6. *Development expenditure once capitalization criteria are met—Scenario 2*

Background



Company A has developed a vaccine delivery device and is now continuing expenditure on the device to add new functionality. The additional functionality will require Company A to receive regulatory approval prior to selling the device.

Should Company A capitalize these development costs? ↓



Solution

No. Company A should expense as incurred the costs of adding new functionality as these costs are research and development expenditures.

Relevant guidance



Research and development costs... shall be charged to expense when incurred [ASC 730-10-25-1].

Expenses are outflows or other using up of assets or incurrences of liabilities (or a combination of both) from delivering or producing goods, rendering services, or carrying out other activities that constitute the entity's ongoing major or central operations [CON 6, par. 80].

7. *Development of alternative indications*

Background



Company A markets a drug approved for use as a painkiller. Recent information shows the drug may also be effective in the treatment of rheumatoid arthritis. Company A has commenced additional development procedures necessary to gain approval for this indication.

Should Company A capitalize the development costs relating to alternative indications? ↓

Relevant guidance



Research and development costs... shall be charged to expense when incurred [ASC 730-10-25-1].

Expenses are outflows or other using up of assets or incurrences of liabilities (or a combination of both) from delivering or producing goods, rendering services, or carrying out other activities that constitute the entity's ongoing major or central operations [CON 6, par. 80].




Solution

No. Costs to perform research and development, including internal development costs, should be expensed as incurred, regardless of history with similar drugs or regulatory expectations.


8. Examples of research and development costs

Background

 Company A is developing a new compound for the treatment of pancreatic cancer. Company A is analyzing its expenditures to determine which expenditures represent research and development costs. These expenditures include costs incurred to identify a new formulation and a routine update to an existing manufacturing line that will be used to make the clinical trial product.

Do the additional expenditures incurred by Company A qualify as research and development costs? ↓

Relevant guidance

 Research and development costs... shall be charged to expense when incurred [ASC 730–10–25–1]. Activities that typically would be considered research and development are included in ASC 730–10–55–1. Some of the examples in ASC 730–10–55–1 include:

- Laboratory research aimed at discovery of new knowledge.
- Searching for applications of new research findings or other knowledge.
- Conceptual formulation and design of possible product or process alternatives.
- Testing in search for or evaluation of product or process alternatives.
- Modification of the formulation or design of a product or process.
- Design, construction, and operation of a pilot plant that is not of a scale economically feasible to the entity for commercial production.
- 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.




Solution

Research and development costs could include materials, equipment or facility charges, compensation and benefits for personnel, intangible assets purchased from others (if they do not have alternative use or have not achieved technological feasibility), the cost of contract services performed by others and a reasonable allocation of indirect costs.

Company A determined that the cost associated with the identification of a new formulation would be expensed as research and development costs, while the cost associated with the routine update to the manufacturing line would be expensed to cost of sales.

9. Asset acquisition of a compound

Background

 Company A acquired a license to the intellectual property rights to a compound for \$5 million on January 1, 20X7. Assume there is no alternative future use and that the acquired asset does not constitute a business. Company A expects to receive regulatory and marketing approval on March 1, 20X8 and plans to start using the compound in its production process on June 1, 20X8.


How should Company A account for the acquisition of the compound? ↓



Solution

Because the license to the compound was acquired prior to regulatory approval, the payment would be expensed as research and development costs (since there is no alternative future use and the acquired asset does not constitute a business). If the license to the compound had been acquired after regulatory approval, Company A would begin amortizing the intangible asset on the date it is available for its expected use. This would generally be the acquisition date for an approved compound.

Relevant guidance


 Intangible assets purchased from others (not in a business combination) for use in research and development activities follow the guidance in ASC 730, *Research and Development*. Assets that have future alternative use are accounted for in accordance with the guidance in ASC 350, *Intangibles—Goodwill and Other*.

The useful life of an intangible asset to an entity is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of that entity [ASC 350-30-35-2].

The method of amortization shall reflect the pattern in which the economic benefits of the intangible asset are consumed or otherwise used up [ASC 350-30-35-6].


10. Accounting for a sales based milestone payment

Background

 Company A acquires the intellectual property rights to one of Company B's completed compounds for an upfront cash payment of \$15 million and agrees to make an additional one time sales based milestone payment of \$10 million if and when sales for the related product in any one year reach a specified sales target level. In this case, Company A has determined that the transaction does not constitute a business and, therefore, will account for it as an asset acquisition. The sales based milestone payment, if made, does not entitle Company A to additional intellectual property rights beyond those already obtained in the initial asset acquisition. Rather, the payment is in effect a one-time royalty since it is due to Company B for the achievement of a specified sales level of the underlying compound.

Company A capitalizes the \$15 million payment made to acquire the IP rights since the rights relate to a completed compound and the cost is considered recoverable based on expected future cash flows. The useful life of the intellectual property rights is 15 years and Company A begins amortizing \$1 million per year. At the end of the third year, following a significant uptick in sales of the product, it becomes probable that the specified sales level will be met the following year.

Relevant guidance

 ASC 450-20-25-2 requires that an estimated loss from a loss contingency be accrued by a charge to income if both of the following conditions are met:

- Information available before the financial statements are issued or are available to be issued indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements.
- The amount of loss can be reasonably estimated.

10. Accounting for a sales based milestone payment (continued)

How should Company A account for the \$10 million sales based milestone payment? ↓



Solution

Company A follows a practice of accruing the sales based milestone payment when it becomes probable that it will be paid. The obligation to make the milestone payment, while contingent on the company reaching a specified sales level, is considered to be established on the date the agreement to make the payment is entered into. Accordingly, at that date, Company A concludes that it has a contractual contingent obligation, based on having received the intellectual property license rights, and accrues the additional amount when payment is no longer contingent. In this case, that occurred when it became probable that the payment will be made. The amount of the payment is reasonably estimable, as it is a fixed amount under the terms of the arrangement once the sales target has been achieved.

After concluding that the sales based milestone should be accrued, Company A would then consider the economics of the arrangement to determine the expense recognition pattern. Because \$25 million is the total consideration paid for the intellectual property rights, it would be appropriate to adjust the carrying value of the intellectual property rights on a cumulative catch-up basis as if the additional amount that is no longer contingent had been accrued from the outset of the arrangement when the obligation was established. Accordingly, Company A would immediately expense 20% (3 out of 15 years) of the \$10 million sales based milestone and capitalize the remainder of the payment. At the end of the third year, Company A would have expensed an aggregate of \$5 million, and \$20 million remains capitalized on the balance sheet. Alternatively, if the economics of the arrangement were such that the payment appeared to be the equivalent of an additional royalty to be paid annually, it would be appropriate to expense the \$10 million payment over the relevant annual period. This might be the case, for example, if there were similar sales based milestone targets in each year of the arrangement.

As a general rule, a view to amortize the \$10 million payment prospectively over the remaining term (twelve years in this example) would only potentially be supportable if the payment was in exchange for additional intellectual property rights under the arrangement.

11. Indefinite-life intangible assets

Background



Management of a pharmaceutical entity has acquired an intangible asset that it believes to have an indefinite useful life.

Relevant guidance



If no legal, regulatory, contractual, competitive, economic or other factors limit the useful life of an intangible asset to the reporting entity, the useful life of the asset shall be considered to be indefinite. The useful life of an intangible asset is indefinite if that life extends beyond the foreseeable horizon—that is, there is no foreseeable limit on the period of time over which it is expected to contribute to the cash flows of the reporting entity [ASC 350–30–35–4].

If an intangible asset is determined to have an indefinite useful life, it shall not be amortized until its useful life is determined to be no longer indefinite [ASC 350–30–35–15].

An entity shall evaluate the remaining useful life of an intangible asset that is not being amortized each reporting period to determine whether events and circumstances continue to support an indefinite useful life [ASC 350–30–35–16].

An intangible asset that is not subject to amortization shall be tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired [ASC 350–30–35–18].

What is required to conclude that an asset has an indefinite useful life, and if so, how should management account for it? ↓



Solution

An asset is regarded as having an indefinite life if there are no factors (as cited above) that would limit its useful life. If an asset has an indefinite life, management is required to test it for impairment by comparing its fair value with its carrying value both annually and more frequently if there is an indication that the intangible asset may be impaired. Pharmaceutical intangible assets that might be regarded as having an indefinite life could include acquired brands (e.g., over-the-counter products) or generic products. Technological and medical advances will reduce the number of situations where an indefinite life would apply. As a result of limited patent lives, only in exceptional cases would prescription pharmaceutical products have indefinite economic lives.

12. Indicators of impairment for intangibles

Background



Company A has capitalized the cost of acquiring the license rights to a product that has recently received regulatory approval.

Company A has plans to begin selling this product in six months, and as such, is not amortizing the asset since it is not available for use.

Relevant guidance



An intangible asset that is subject to amortization shall be reviewed for impairment in accordance with the impairment or disposal of long-lived assets subsections of ASC 360-10 by applying the recognition and measurement provisions in paragraphs 360-10-35-17 through 35-35 [ASC 350-30-35-14].

An impairment loss shall be recognized only if the carrying amount of a long-lived asset (asset group) is not recoverable and exceeds its fair value. The carrying amount of a long-lived asset (asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset (asset group). That assessment shall be based on the carrying amount of the asset (asset group) at the date it is tested for recoverability, whether in use or under development. An impairment loss shall be measured as the amount by which the carrying amount of a long-lived asset (asset group) exceeds its fair value [ASC 360-10-35-17].

A long-lived asset (asset group) shall be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable [ASC 360-10-35-21].

What indicators of impairment should management consider? ↓



Solution

ASC 360-10-35-21 provides several examples of events or changes in circumstances (not all-inclusive) that management should consider when assessing whether an intangible asset should be tested for impairment. Some of the events or changes in circumstances include: a significant decrease in the market price of the long-lived asset, a significant adverse change in the manner in which the asset is used or a significant adverse legal event.

Management of pharmaceutical and life sciences entities should also consider other industry-specific indicators, including:

- Development of a competing drug;
- Changes in the legal framework covering patents, rights, or licenses;
- Failure of the drug's efficacy;
- Advances in medicine and/or technology that affect the medical treatments;
- A pattern of lower than predicted sales;
- Change in the economic lives of similar assets;
- Relationship with other intangible or tangible assets; and
- Changes or anticipated changes in participation rates or reimbursement policies of insurance companies, Medicare or the government.

13. Indicators of impairment – Property, plant and equipment

Background



Company A announced a withdrawal of a marketed product due to unfavorable post-approval Phase IV study results. Company A informed healthcare authorities that patients should no longer be treated with that product. Company A has property, plant and equipment that is dedicated specifically to the production of the terminated product and has no future alternative use.

Relevant guidance



A long-lived asset (asset group) shall be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable [ASC 360-10-35-21].

What impairment indicators should Company A consider? ↓



Solution

Company A should consider the general indicators given in ASC 360-10-35-21 when assessing whether there is an impairment of property, plant and equipment. In addition, pharmaceutical and life sciences entities should consider industry-specific factors such as the following:

- Patent expiry date;
- Failure of the machinery to meet regulatory requirements;
- Technical obsolescence of the property, plant and equipment (for example, because it cannot accommodate new market preferences);
- Changes in medical treatments;
- Market entrance of competitive products;
- Product recall; and
- Changes or anticipated changes in third-party reimbursement policies that will impact the price received for the sale of product manufactured by the property, plant and equipment.

As a result of withdrawing the product, Company A determined that the property, plant and equipment was fully impaired as it is dedicated specifically to the production of the terminated product and therefore there were no future cash flows associated with the long-lived asset group.

14. Single market impairment

Background

i Company A acquired the rights to market a topical fungicide cream in Europe. The acquired rights apply broadly to the entire territory and, as such, Company A determined that it would account for the acquired right as one unit of account. For unknown reasons, patients in Country X prove far more likely to develop blisters from use of the cream, causing Company A to withdraw the product from that country. As fungicide sales in Country X were not expected to be significant, the loss of the territory, taken in isolation, does not cause the overall value from sales of the drug to be less than its carrying value.

What is the impact of the withdrawal of a drug from a specific territory on Company A's impairment analysis? ↓

Relevant guidance

⚡ A long-lived asset (asset group) shall be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable [ASC 360-10-35-21].

An impairment loss shall be recognized only if the carrying amount of a long-lived asset (asset group) is not recoverable and exceeds its fair value. The carrying amount of a long-lived asset (asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset (asset group) [ASC 360-10-35-17].

For purposes of recognition and measurement of an impairment loss, long-lived asset or assets shall be grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities [ASC 360-10-35-23].



Solution

Company A acquired the rights to market the fungicide cream over a broad territory and not specifically in Country X. Therefore, the entire territory would likely represent the lowest level of identifiable cash flows for testing impairment of the marketing rights. Because revenues from product sales in Country X were not significant, the withdrawal of the product from Country X's market would not be considered a triggering event that would require an impairment analysis to be performed.

However, Company A should carefully consider whether the development of blisters in patients in Country X is indicative of potential problems in other territories. If the issue cannot be isolated, a triggering event would be considered to have occurred and a broader impairment analysis should be performed, including the consideration of the potential for more wide-ranging decreases in sales.

15. Impairment testing and useful life

Background

i Company A has a major production line that produces its blockbuster antidepressant. The production line has no alternative use. A competitor launches a new antidepressant with better efficacy. Company A expects sales of its drug to drop rapidly and significantly. Although positive margins are forecasted to continue, Company A identifies this as an indicator of impairment. As a result of the new competition, Company A may exit the market for this drug earlier than previously contemplated.

How should Company A assess the impairment and useful lives of long-lived assets where impairment indicators have been identified? ↓

Relevant guidance

⚡ A long-lived asset (asset group) shall be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable [ASC 360-10-35-21].

An impairment loss shall be recognized only if the carrying amount of a long-lived asset (asset group) is not recoverable and exceeds its fair value. The carrying amount of a long-lived asset (asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset (asset group)... An impairment loss shall be measured as the amount by which the carrying amount of a long-lived asset (asset group) exceeds its fair value [ASC 360-10-35-17].

When a long-lived asset (asset group) is tested for recoverability, it also may be necessary to review depreciation estimates and method... or the amortization period... Any revision to the remaining useful life of a long-lived asset resulting from that review also shall be considered in developing estimates of future cash flows used to test the asset (asset group) for recoverability... [ASC 360-10-35-22].

If an impairment loss is recognized, the adjusted carrying amount of a long-lived asset shall be its new cost basis. For a depreciable long-lived asset, the new cost basis shall be depreciated (amortized) over the remaining useful life of that asset. Restoration of a previously recognized impairment loss is prohibited [ASC 360-10-35-20].



Solution


Assuming that the antidepressant asset group represents the lowest level of identifiable cash flows, Company A should evaluate the carrying amount of the antidepressant's asset group (including the production line) relative to its future undiscounted cash flows. An impairment loss should be recognized if the carrying amount of the antidepressant's asset group exceeds the future undiscounted cash flows. The resulting impairment would be based on the difference between the carrying amount of the unit and its fair value.

Company A should revise the estimated useful life of the affected assets remaining after the impairment analysis is performed based on the estimated period it expects to obtain economic benefit from the assets. After recognizing the impairment and revising the estimated useful life for the affected assets, Company A would continue to amortize the remainder of the asset over its expected useful life.

However, regardless of whether there is an impairment recognized as a result of the impairment analysis, Company A should assess the useful life of the assets based on the estimated period it expects to obtain economic benefit from the assets and revise the useful life as necessary.


16. Exchange of intangible assets

Background

 Company A is developing a hepatitis vaccine compound. Company B is developing a measles vaccine compound. Company A and Company B enter into an agreement to swap the two products. Company A and Company B will not have any continuing involvement in the products that they have swapped. The fair value of Company A's compound has been assessed as \$3 million. The carrying value of Company A's compound was zero, as it was internally developed.

How should Company A account for the swap of vaccine products, assuming that the transaction has commercial substance? ↓

Relevant guidance

 The cost of a nonmonetary asset acquired in exchange for another nonmonetary asset is the fair value of the asset surrendered to obtain it, and a gain or loss shall be recognized on the exchange. The fair value of the asset received shall be used to measure the cost if it is more clearly evident than the fair value of the asset surrendered [ASC 845-10-30-1].

A nonmonetary exchange shall be measured based on the recorded amount... of the nonmonetary asset(s) relinquished, and not on the fair values of the exchanged assets, and not on the fair values of the exchanged assets, if any of the following conditions apply]:

- The fair value of neither the asset(s) received nor the asset(s) relinquished is determinable within reasonable limits.
- The transaction is an exchange of a product or property held for sale in the ordinary course of business for a product or property to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange.
- The transaction lacks commercial substance [ASC 845-10-30-3].

A nonmonetary exchange has commercial substance if the entity's future cash flows are expected to significantly change as a result of the exchange [ASC 845-10-30-4].




Solution

Company A should recognize the compound received at the fair value of the compound given up, which is \$3 million. Company A should also recognize a gain on the exchange of \$3 million (\$3 million–zero book value for the compound Company A gave up) because Company A has no continuing involvement or additional obligations with respect to the product given up.


17. Exchange of intangible assets with continuing involvement

Background

 Company A is developing a hepatitis vaccine compound. Company B is developing a measles vaccine compound. Company A and Company B enter into an agreement to swap these two compounds. Under the terms of the agreement, Company A will retain the marketing rights to its hepatitis vaccine compound for all Asian countries. The fair value of Company A's compound has been assessed as \$3 million, including \$1 million relating to the Asian marketing rights. The carrying value of Company A's compound was zero, as it was internally developed. The transaction does not constitute the sale of a business.

How should Company A account for the swap of vaccine compounds, assuming that the transaction has commercial substance? ↓

Relevant guidance

 The cost of a nonmonetary asset acquired in exchange for another nonmonetary asset is the fair value of the asset surrendered to obtain it, and a gain or loss shall be recognized on the exchange. The fair value of the asset received shall be used to measure the cost if it is more clearly evident than the fair value of the asset surrendered [ASC 845-10-30-1].

A nonmonetary exchange shall be measured based on the recorded amount... of the nonmonetary asset(s) relinquished, and not on the fair values of the exchanged assets, and not on the fair values of the exchanged assets, if any of the following conditions apply]:

- The fair value of neither the asset(s) received nor the asset(s) relinquished is determinable within reasonable limits.
- The transaction is an exchange of a product or property held for sale in the ordinary course of business for a product or property to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange.
- The transaction lacks commercial substance [ASC 845-10-30-3].

A nonmonetary exchange has commercial substance if the entity's future cash flows are expected to significantly change as a result of the exchange [ASC 845-10-30-4].



Solution

Company A should recognize the compound received at the fair value of the compound given up, which is \$2 million (\$3 million–\$1 million). The fair value of \$1 million relating to the Asian marketing rights is excluded from the calculation because the rights have not been sold.

Company A needs to assess whether it has continuing involvement related to the compound it had exchanged to determine the appropriate accounting for the gain on the exchange of \$2 million (\$2 million–zero book value for the compound Company A gave up). If Company A determines it has continuing involvement, the gain would be deferred and recognized over the continuing involvement period. The SEC Staff has reiterated that ASC 845, *Nonmonetary Transactions*, is a measurement standard and does not address the timing of revenue or gain recognition. Company A would need to assess the “earned” and “realized” criteria of CON 5, *Recognition and Measurement in Financial Statements of Business Enterprises*, and the “transfer of control” criteria of ASC 606 to determine the appropriate recognition timing.

18. Accounting for receipt of listed shares in exchange for a patent

Background



Company A agrees to acquire a patent from Company B in order to develop a drug. Company A will pay for the right it acquires by giving Company B 5% of its shares (which are listed and not subject to any restrictions). Company B is in the business of licensing and selling patents in its patent portfolio; therefore, Company A is considered a customer. The listed shares are considered to be equal in value to the patent. If Company A is successful in developing a drug and bringing it to the market, Company B will receive a 5% royalty on all sales. Company B expects to classify the shares as available-for-sale securities.

Relevant guidance



If a security is acquired with the intent of selling it within hours or days, the security shall be classified as trading. However, at acquisition an entity is not precluded from classifying as trading a security it plans to hold for a longer period. Classification of a security as trading shall not be precluded simply because the entity does not intend to sell it in the near term [ASC 320-10-25-1a].

Investments in debt securities and equity securities that have readily determinable fair values not classified as trading securities or as held-to-maturity securities shall be classified as available-for-sale securities [ASC 320-10-25-1b].

The cost of a nonmonetary asset acquired in exchange for another nonmonetary asset is the fair value of the asset surrendered to obtain it, and a gain or loss shall be recognized on the exchange. The fair value of the asset received shall be used to measure the cost if it is more clearly evident than the fair value of the asset surrendered [ASC 845-10-30-1].

To determine the transaction price for contracts in which a customer promises consideration in a form other than cash, an entity shall measure the estimated fair value of the noncash consideration at contract inception [ASC 606-10-32-21].

An entity shall include in the transaction price some or all of an amount of variable consideration estimated only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved [ASC 606-10-32-11].

18. Accounting for receipt of listed shares in exchange for a patent (continued)

How should Company B account for this transaction? ↓



Solution

Company B should initially recognize the shares received as available-for-sale securities. Company B should also derecognize the patent that is transferred to Company A to the extent an asset has been previously recorded.

Company B concluded that Company A is a customer. In accordance with ASC 606, Company B should initially recognize as revenue the estimated fair value of the shares received (i.e., the noncash consideration).

To the extent Company B can estimate a minimum amount of royalties it expects to receive and it is probable that the amount will not result in a significant reversal of cumulative revenue in the future, such estimated amounts are included in the transaction price at the time of sale. Company B should update its assessment for these royalties at each reporting date. Since the transaction is a sale of IP and not a license, the sales- and usage-based royalty exception does not apply.

19. Accounting for receipt of unlisted shares in exchange for a patent

Background



Company A agrees to acquire a patent from Company B in order to develop a drug. Company A will pay for the right it acquires by giving Company B 10% of the shares in an unlisted subsidiary. Company B does not typically sell patents in its patent portfolio. If Company A is successful in developing a drug and bringing it to the market, Company B will receive a 5% royalty on all sales. Company B expects to classify these shares as a cost method investment.

Relevant guidance



The fair value of an equity security is readily determinable if sales prices or bid-and-asked quotations are currently available on a securities exchange registered with the U.S. Securities and Exchange Commission (SEC) or in the over-the-counter market, provided that those prices or quotations for the over-the-counter market are publicly reported by the National Association of Securities Dealers Automated Quotations systems or by OTC Markets Group Inc. [ASC 320-10-20].

An investment in the stock of an investee... shall be measured initially at cost [ASC 325-20-30-1].

The cost of a nonmonetary asset acquired in exchange for another nonmonetary asset is the fair value of the asset surrendered to obtain it, and a gain or loss shall be recognized on the exchange. The fair value of the asset received shall be used to measure the cost if it is more clearly evident than the fair value of the asset surrendered [ASC 845-10-30-1].

When an entity meets the criteria to derecognize a distinct nonfinancial asset or a distinct in substance nonfinancial asset, it shall recognize a gain or loss for the difference between the amount of consideration measured and allocated to that distinct asset and the carrying amount of the distinct asset. The amount of consideration promised in a contract that is included in the calculation of a gain or loss includes both the transaction price and the carrying amount of liabilities assumed or relieved by a counterparty [ASC 610-20-32-2].

To determine the transaction price, an entity shall apply the following paragraphs in Topic 606 on revenue from contracts with customers: Paragraphs 606-10-32-2 through 32-27 on determining the transaction price, including (1) estimating variable consideration, (2) constraining estimates of variable consideration... and (3) noncash consideration [ASC 610-20-32-3].

19. Accounting for receipt of unlisted shares in exchange for a patent (continued)

How should Company B account for this transaction? ↓



Solution

Generally, the fair value of the patent given up will likely be more readily determinable than the fair value of the shares because these shares are of an unlisted subsidiary. ASC 320 states that fair value is only deemed readily determinable if sales prices or bid-and-asked quotations are currently available on a securities exchange registered with the Securities and Exchange Commission or in the over-the-counter market, or similar foreign market.

Company B would generally be expected to conclude that the fair value of the shares is the same value as the patent given up. As Company B is not in the business of licensing and selling patents in its portfolio, Company B should recognize the gain arising from the sale of the patent (fair value less carrying value of the patent) as a gain on sale of long-lived assets (separately stated, if material) or as other income.

Company B determined that Company A is not a customer. Upon the adoption of ASC 610-20, *Gains and losses from the derecognition of nonfinancial assets*, Company B should initially recognize as a component of the gain calculation the estimated fair value of the shares received (i.e., the noncash consideration).

To the extent Company B can estimate a minimum amount of royalties it expects to receive and it is probable that the amount will not result in a significant reversal of cumulative revenue in the future, such amount is included in the gain calculation at the time of sale. Company B should update its assessment for these royalties at each reporting date.

Refer to ASC 610-20 Example 3 – *Sale of a nonfinancial asset for variable consideration* for additional guidance on this topic.

A laboratory setting with various scientific equipment. In the foreground, there are several containers: a blue cylindrical container labeled 'Micro Applicators' with a white cap, a smaller container with green and white applicators, and a brown bottle with a white cap. A blue tray with a yellow circle is also visible. The background is blurred, showing more laboratory equipment and a white bag.

*Research and
development*

20. In-licensing agreements

Background



Company A and Company B enter into an agreement in which Company A will license Company B's know-how and technology to manufacture a compound to treat HIV. It cannot use the know-how and technology for any other project or otherwise assign or transfer the know-how and technology. Company A has not yet concluded that economic benefits are likely to flow from this compound or that relevant regulatory approval will be achieved.

Company A will use Company B's technology in its facilities for a period of three years. The agreement stipulates that Company A will make a non-refundable payment of \$3 million to Company B for access to the technology. Company B will also receive a 20% royalty from all future sales of the compound.

Relevant guidance



ASC 730-10-25-1 *Research and Development* states that "Research and development costs... shall be charged to expense when incurred."

ASC 730-10-25-2c requires that the costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses and thus have no separate economic values, are research and development costs at the time the costs are incurred.

How should Company A account for the in-licensing agreement? ↓




Solution

Company A should expense the \$3 million when incurred as research and development costs since the know-how and technology have no alternative future uses.


The royalty payments of 20% of sales are generally presented in the income statement within cost of sales.

21. Non-refundable upfront payments to conduct research (from an unrelated investor)

Background

 Company A engages a contract research organization (CRO) to perform research activities for a period of two years in connection with a drug compound related to the treatment of HIV. The CRO is well known in the industry for having modern facilities and good practitioners dedicated to investigation. The CRO receives a non-refundable, upfront payment of \$3 million in order to carry out the research under the agreement. It will have to present a quarterly report to Company A with the results of its research. Company A has full rights to the research performed, including an ability to control the research undertaken on the potential cure for HIV. The CRO has no rights to use the results of the research for its own purposes.

Relevant guidance

 ASC 730-10-25-1 *Research and development* states that “Research and development costs... shall be charged to expense when incurred.”

ASC 730-20-25-13 *Research and development arrangements* indicates that “Non-refundable advance payments for goods or services that have the characteristics that will be used or rendered for future research and development activities pursuant to an executory contractual arrangement shall be deferred and capitalized.”

How should Company A account for the upfront payments made to the CRO? ↓



Solution

Although the payment is non-refundable, Company A will receive a future benefit as the CRO performs the research services over the two-year period. Therefore, the upfront payment should be capitalized and recognized in the income statement (as research and development expense) using the straight-line method, unless another method is more reflective of the CRO’s effort. Company A should continue to evaluate whether it expects the goods to be delivered or services to be rendered each reporting period to assess recoverability and classification of the asset.

If the payment or portion of the payment from Company A to CRO represented an advance payment for specific materials, equipment or facilities that do not have an alternative future use, this payment or portion of the payment would be recognized in the income statement as research and development expense at the time of payment.

22. *Non-refundable upfront payments to conduct research (from a related party)*

Background



Company A plans to perform research activities for a period of two years in order to obtain know-how and to discover a cure for HIV. Company A receives a non-refundable, upfront payment of \$3 million from a related party in order to carry out the research and development activities. Company A has full rights to the research performed, including an ability to control the research undertaken on the potential cure for HIV. The related party has no rights to use the results of the research for its own purposes.

How should Company A account for the upfront payments made by the related party? ↓

Relevant guidance



ASC 730-20-25-3 *Research and development arrangements* states that “If 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.”

ASC 730-20-25-6 *Research and development arrangements* states that “Examples of conditions leading to the presumption that the entity will repay the other parties include any of the following... 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.”



Solution

Although the payment is non-refundable, Company A has received the payment from a related party. There is a presumption that Company A has an obligation to repay these non-refundable amounts to the related party and, therefore, should recognize a liability. This requirement applies whether Company A settles the liability by paying cash, by issuing securities, or by some other means. This presumption of repayment can be overcome only by substantial evidence to the contrary.

Company A should charge their research and development costs to expense as incurred.

23. Payments made to conduct research

Background



Company A, a small pharmaceutical company, is engaged by Company B, a large pharmaceutical company, to develop a new medical treatment for migraines over a five-year period. Company A is engaged only to provide research and development services and will periodically have to update Company B with the results of its work. Company B has exclusive rights over the development results. Company B will make 20 equal non-refundable quarterly payments of \$0.25 million (totaling \$5 million), if Company A can demonstrate compliance with the development program for the respective quarterly period. Payments do not depend upon the achievement of a particular outcome.

Relevant guidance



ASC 730-10-25-1 *Research and development* states that “Research and development costs... shall be charged to expense when incurred.”

How should Company B recognize the payments it makes to Company A? ↓



Solution

Company B should recognize research and development expense of \$0.25 million each quarter with no amount capitalized for as long as it authorizes Company A to continue performing the research.

24. Fixed-fee contract research arrangements

Background



Company A enters into a contract research arrangement with Company B. Company B will perform research on a library of molecules and will catalogue the research results in a database.

Company A will pay Company B \$3 million only upon completion of the contracted work. The payment is based on delivery of the research services. There are no success-based contingencies.

Relevant guidance



Under ASC 730-10-25-2(d), 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 [on] behalf of the entity, shall be included in research and development costs.

How should Company A account for the contract research arrangement? ↓




Solution

The costs of the contract research arrangement should be recorded as research expenses by Company A as Company B performs the services. Company A should accrue the contract research costs over the expected period of the research. Company A will need some visibility into Company B's pattern of performance in order to properly expense the contract research costs under the arrangement. The structuring of the payment(s) does not alter the accounting treatment.


25. Third-party development of intellectual property

Background

 Company A has appointed Company B, an independent third party, to develop an existing compound owned by Company A on its behalf. Company B will act purely as a service provider without taking any risks during the development phase and will have no further involvement after regulatory approval. Company A will retain full ownership of the compound. Company B will not participate in any marketing or production arrangements. Company A agrees to make the following non-refundable payments to Company B:

- \$2 million on signing the agreement.
- \$3 million on successful completion of Phase II testing.

Relevant guidance

 Research and development costs shall be charged to expense when incurred [ASC 730-10-25-1].

Nonrefundable advance payments for goods or services that have the characteristics that will be used or rendered for future research and development activities pursuant to an executory contractual arrangement shall be deferred and capitalized [ASC 730-20-25-13].

How should Company A account for upfront and subsequent milestone payments in an arrangement in which a third party develops its intellectual property? ↓



Solution

The initial upfront payment represents a prepayment for future development by a third party and should be capitalized initially and then amortized as Company B performs the research (i.e., generally straight line over the expected period of performance unless another recognition pattern more accurately depicts performance). Company A should generally expense the milestone payment when it is probable the payment will be made unless the milestone payment is intended to compensate for future development services. In such instances, Company A should capitalize the milestone payment and amortize it over the performance period in a pattern that accurately depicts the underlying performance.

26. Recording a milestone payment due to a counterparty

Background



Company A entered into a collaboration arrangement with Company B. Company A paid Company B an upfront fee upon signing the arrangement and will pay Company B a discrete milestone payment of \$2 million upon FDA approval.

When should Company A record the milestone payment due to Company B? ↓



Solution

The milestone payment is due under the contractual terms of the agreement based upon the resolution of a contingency. Company A should accrue the milestone payment when the achievement of the milestone is probable (the amount of the payment is reasonably estimable, as it is a fixed amount under the terms of the arrangement). Once Company A concludes that the milestone payment due to Company B is probable of occurring, the amount of the payment (\$2 million in this example) would be recorded in the financial statements.

Due to the uncertainties associated with the FDA approval process, it may be the case that it is difficult for Company A to conclude that achievement of this particular milestone is probable prior to the occurrence of the event that triggers the milestone (e.g., notification of FDA approval). All facts and circumstances regarding the nature of the milestone should be considered when evaluating when the achievement of a milestone is probable.

Relevant guidance



ASC 450-20-25-2 requires that an estimated loss from a loss contingency be accrued by a charge to income if both of the following conditions are met:

- Information available before the financial statements are issued or are available to be issued indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements.
- The amount of the loss can be reasonably estimated.

27. External development of intellectual property with buy-back options

Background



Company A has out-licensed the development of an existing compound to Company B, an independent third party. There was no upfront consideration paid between the parties. Company A will neither retain any involvement in the development of its compound nor participate in the funding of the development. However, in the case of successful completion of the development as evidenced by regulatory approval in the key markets, Company A has the option to buy-back the rights to its compound. The following terms are agreed:

- If the development fails, Company B bears all the costs it incurred without any compensation.
- If the development is successful and Company A exercises its buy-back option, Company B receives an agreed buy-back payment (as well as future sales based milestone payments and royalty streams).
- If the development is successful and Company A does not exercise the option, Company B can commercialize the compound on its own (paying milestones and royalties to Company A under the license arrangement).

Relevant guidance



If 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 730-20-25-3].

To conclude 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. To 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 [ASC 730-20-25-4].

The following are examples of conditions leading to the presumption that an entity will repay the other parties [ASC 730-20-25-6]:

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

27. External development of intellectual property with buy-back options (continued)

Relevant guidance



If the entity's obligation is to perform research and development for others and the entity subsequently decides to exercise an option to purchase the other parties' interests in the research and development arrangement or to obtain the exclusive rights to the results of the research and development, the nature of those results and their future use shall determine the accounting for the purchase transaction or business combination... [ASC 730-20-25-9].

How should Company A account for payments in an arrangement in which a third party develops its intellectual property? ↓

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 [on] behalf of the entity, shall be included in research and development costs [ASC 730-10-25-2(d)].



Solution

Company A effectively removes its exposure to failure of the development of its compound, having transferred all development risks to Company B. In this case, there are no indicators that would lead to a presumption that the buyback will occur and that a liability should be recognized before any decision to reacquire the rights were to occur.

Through exercise of the buy-back option, Company A reacquires the commercialization right intangible asset. Since exercise of the buy-back option is triggered upon regulatory approval, the buyback payment would be capitalized when contractually due and then amortized over the useful life of the commercialization right.

28. Donation payment for research

Background



Company A has made a non-refundable gift of \$3 million to a university. The donation is to be used to fund research activities in the area of infectious diseases over a two-year period. Company A has no right to access the research findings.

Relevant guidance



ASC 720-25-25-1 states that a contribution shall be recognized as an expense and as either a decrease in assets or increase in liabilities (depending on the form of benefits given) in the period during which the contribution is made. Unconditional promises to give cash, for example, are recognized as payables and contribution expenses.

How should Company A recognize the donation? ↓



Solution

Company A should expense the donation when incurred (normally when paid) or at the time an unconditional promise to give cash is made, whichever is sooner, in the income statement (generally as selling, general and administrative expense).

29. Capitalization of interest incurred on loans received to fund research and development

Background



Company A has obtained a loan from Company B, another pharmaceutical company, to finance the late-stage development of a drug to treat cancer.

Can Company A capitalize the interest incurred for borrowings obtained to finance research and development activities? ↓

Relevant guidance



Interest shall be capitalized for the following types of assets (“qualifying assets”) [ASC 835–20–15–5]:

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




Solution

Borrowing costs associated with research and development projects are expensed as incurred as they do not qualify for capitalization.


30. Treatment of trial batches in development

Background

 Company A, a commercial laboratory, is manufacturing a stock of 20,000 doses (trial batches) of a newly developed drug, using various raw materials. The doses can only be used in patient trials during Phase III clinical testing, and cannot be used for any other purpose. The raw materials can be used in the production of other approved drugs.

How should Company A account for the raw materials and trial batches? ↓

Relevant guidance

 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...

However, the cost 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 [ASC 730-10-25-2(a)].



Solution

Company A should initially recognize the raw materials acquired for the production of trial batches as inventory since the raw materials have alternative future use in the production of other approved drugs. As the trial batches do not have any alternative future use and the technical feasibility of the drug is not proven (the drug is in Phase III), the trial batches (including the cost of raw materials used in their production) should be charged to development expense when they are produced.

31. Accounting for funded research and development arrangements

Background



Company A partners with Investor B, an unrelated financial investor, for the development of selected compounds that are in Phase II development. Investor B commits a specified dollar amount to fund the research and development of the selected compounds. In exchange for the funding, Investor B will receive royalties on future sales of product resulting from the compounds being developed. Investor B will not receive any repayment if the compounds are not successfully developed (i.e., the transfer of financial risk for the research and development is substantive). Investor B does not participate in any of the development or commercialization activities.

Relevant guidance



ASC 730–20, *Research and Development Arrangements*, provides guidance on accounting for research and development arrangements through which a company can obtain the results of the research and development funded partially or entirely by others. This guidance requires a company to determine the nature of the obligation it incurs when it enters into a research and development funding arrangement to ascertain whether the obligation is (i) a liability to repay the funding party or (ii) to perform contractual services.

ASC 470–10–25, *Debt*, provides guidance on the accounting for cash received from an investor when a company agrees to pay the investor, for a defined period, a specified percentage or amount of revenue of a particular product line, business segment, trademark, patent, or contractual right. This guidance discusses whether cash proceeds received from a sale of future revenues should be classified as debt or deferred income.

31. Accounting for funded research and development arrangements (continued)

What factors should Company A consider to determine the most appropriate accounting model for the research and development funding? ↓



Solution

While ASC 730–20 only relates to research and development funding, ASC 470–10–25 does not specifically exclude research and development funding arrangements from its scope. If the research and development risk is substantive, such that it is not yet probable the development will be successful, the guidance in ASC 730–20 shall be followed. However, if the successful completion of the research and development is already probable at the time the funding is received, the guidance in ASC 470–10–25 is most applicable.

To conclude that a liability does not exist, the transfer of financial risk involved with the research and development from Company A to Investor B must be substantive and genuine. When assessing the substance of the transfer of financial risk, Company A should consider any explicit or implicit obligations to repay any or all of the funding. If surrounding conditions suggest that it is probable that Company A will repay any of the funds regardless of the outcome of the research and development, the funding should be recorded as a liability. Assessing the probability of repayment requires significant judgment and will be based on the facts and circumstances of the transaction.

Examples of conditions leading to a presumption that repayment is probable include the following:

- Company A has indicated an intent to repay all or a portion of the funds regardless of the outcome of the research and development;
- Company A would suffer a severe economic penalty if it failed to repay any of the funds provided to it regardless of the outcome of the research and development;
- A significant related party relationship exists between the parties at the time the entity enters into the arrangement (in this scenario Company A and Investor B are unrelated); and
- Company A has essentially completed the project before entering into the arrangement.

Given the nature of the development and regulatory process, Company A determines that there is significant risk associated with the research and development and that successful development is not probable. Accordingly, Company A will apply the guidance in ASC 730–20 to evaluate the accounting for the research and development funding (i.e., whether it is a liability to repay the funding party or an obligation to perform contractual services).


In this example, Company A has no explicit or implicit obligation to repay any of the funds and therefore determines that the arrangement is an obligation to perform contractual research and development services.



Manufacturing

32. Treatment of validation batches

Background

 A laboratory has just completed the development of a new machine to mix components at a specified temperature to create a new formulation of aspirin. The laboratory produces several batches of the aspirin, using the new machinery to obtain validation (an approval for the use of the machine) from the relevant regulatory authorities. The validation of the machinery is a separate process from the regulatory approval of the new formulation of aspirin.


Should expenditures to validate machinery be capitalized? ↓



Solution

The laboratory should capitalize the costs incurred (including materials, labor, applicable overhead) to obtain the necessary validation for the use of the machinery, together with the cost of the machinery. Validation is required to bring the machinery to its working condition. However, management should exclude abnormal validation costs caused by errors or rework during the validation process (such as wasted material, labor or other resources). If the machinery requires revalidation, the costs related to this would be expensed as incurred as the asset had already been prepared for its original intended use.

Relevant guidance

 Property, plant, and equipment is reported at historical cost which is the amount of cash, or its equivalent, paid to acquire an asset, commonly adjusted after acquisition for amortization or other allocations [CON 5, par. 67]. This includes directly attributable expenditures incurred in acquiring the equipment and preparing it for use.

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. If an asset requires a period of time in which to carry out the activities necessary to bring it to that condition and location, the interest cost incurred during that period as a result of expenditures for the asset is a part of the historical cost of acquiring the asset [ASC 835-20-05-1].

33. Treatment and presentation of development supplies

Background



A laboratory has purchased 10,000 batches of saline solution. These batches are used in trials on patients during various Phase III clinical tests. They can also be used as supplies for other testing purposes, but have no other uses (i.e., the Company has no intention to sell the batches in the future). Management is considering whether the batches should be recorded as an asset.

Relevant guidance



Inventory is defined as the aggregate of those items of tangible personal property that have any of the following characteristics: (a) held for sale in the ordinary course of business, (b) in process of production for such sale, or (c) to be currently consumed in the production of goods or services to be available for sale [ASC 330-10-20].

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. [ASC 730-10-25-2].

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 [CON 6, par. 26].

Should costs associated with supplies used in clinical testing be accounted for as inventory? ↓



Solution

The batches do not meet the definition of inventory because they are not (1) held for sale in the ordinary course of business; (2) in the process of production for such sale; or (3) currently consumed in the production of goods to be available for sale. However, the batches do meet the definition of an asset (other current asset or prepaid asset) since they have alternative future uses in other development projects. They should therefore be recorded at cost and accounted for as supplies used in the development process. When supplies are used, the associated cost forms part of research and development expense.

34. Pre-launch inventory – Treatment of ‘in-development’ drugs

Background



Company A developed a new drug and needs to have sufficient quantities of inventory on-hand in anticipation of commercial launch once regulatory approval to market the product has been obtained. Company A has filed for regulatory approval and is currently awaiting a decision. Company A believes that final regulatory approval is probable.

Company A produced 15,000 doses following submission of the filing for regulatory approval. If regulatory approval is not obtained, the inventory has no alternative use. Company A measures inventory using FIFO.

Relevant guidance



Assets are probable future economic benefits obtained or controlled by a particular entity as a result of past transactions or events [CON 6, par. 25].

Inventory is defined as the aggregate of those items of tangible personal property that have any of the following characteristics: (a) held for sale in the ordinary course of business, (b) in process of production for such sale, or (c) to be currently consumed in the production of goods or services to be available for sale [ASC 330-10-20].

The primary basis of accounting for inventories is cost, which has been defined generally as the price paid or consideration given to acquire an asset. As applied to inventories, cost means in principle the sum of the applicable expenditures and charges directly or indirectly incurred in bringing an article to its existing condition and location. It is understood to mean acquisition and production cost, and its determination involves many considerations [ASC 330-10-30-1].

Inventory measured using any method other than LIFO or the retail inventory method (for example, inventory measured using first-in, first-out (FIFO) or average cost) shall be measured at the lower of cost and net realizable value. When evidence exists that the net realizable value of inventory is lower than its cost, the difference shall be recognized as a loss in earnings in the period in which it occurs. That loss may be required, for example, due to damage, physical deterioration, obsolescence, changes in price levels, or other causes [ASC 330-10-35-1B].

34. Pre-launch inventory – Treatment of ‘in-development’ drugs (continued)

How should the costs associated with the production of pre-launch inventory for ‘in-development’ drugs be accounted for? ↓



Solution


Pre-launch inventory can be capitalized if it has probable future economic benefit. The assessment of whether pre-launch inventory has probable future economic benefits depends on individual facts and circumstances. Factors to consider include whether key safety, efficacy and feasibility issues have been resolved, status of any advisory committee reviews, and understanding of any potential hurdles to regulatory approval or product reimbursement.

Company A believes that the filing for regulatory approval indicates that future economic benefit is probable. Accordingly, the pre-launch inventory can be capitalized at the lower of cost or net realizable value. Periodic reassessments should be made to determine whether the inventory continues to have a probable future economic benefit (e.g., whether regulatory approval is still probable and whether product will be sold prior to expiration of its useful life). If the value of inventory is written down based on this reassessment, the reduced amount is the new cost basis (i.e., if regulatory approval is ultimately obtained, the inventory is not written back up). If at any time regulatory approval is deemed to not be probable, the inventory should be written down to its net realizable value, which is presumably zero assuming that the product cannot be sold.


Companies should consider whether additional financial statement disclosures are necessary related to the capitalization of pre-launch inventory, including the accounting policy and total amount capitalized. Further, if inventory that had previously been written down is ultimately sold, companies should consider disclosing the impact on margins.

35. Recognition of raw materials as inventory

Background

 Company A buys bulk materials used for manufacturing a variety of drugs. The materials are used for marketed drugs, samples and drugs in development. The materials are warehoused in a common facility and released to production based upon orders from the manufacturing and development departments.

Relevant guidance

 Inventory is defined as the aggregate of those items of tangible personal property that have any of the following characteristics: (a) held for sale in the ordinary course of business, (b) in process of production for such sale, or (c) to be currently consumed in the production of goods or services to be available for sale [ASC 330–10–20].

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 [ASC 730–10–25–2].

How should purchased materials be accounted for when their ultimate use is not known? ↓




Solution

Company A should account for raw materials that can be used in the production of marketed drugs as inventory. When the material is consumed in the production of sample products, Company A should account for the sample product to be given away as an expense in accordance with its policy, which would generally be either when the product is packaged as sample product or the sample is distributed. When the materials are released to production for use in the manufacturing of drugs in development, the cost of the materials should be accounted for as research and development expense.


Alternatively, if the bulk materials were only able to be used for a particular research and development project, and did not have alternative future uses, the costs would be recognized as research and development expense when incurred.

36. Indicators of impairment – Inventory

Background

 Company A has decided to temporarily suspend all operations at a certain production site due to identified quality issues. Company A initiated a recall of products manufactured at that certain site to be destroyed upon return. Additionally, Company A carries a significant amount of raw material inventory used in the manufacturing of the recalled product. There is no work-in-process on hand at the time of suspension.

Relevant guidance

 Inventory measured using any method other than LIFO or the retail inventory method (for example, inventory measured using first-in, first-out (FIFO) or average cost) shall be measured at the lower of cost and net realizable value. When evidence exists that the net realizable value of inventory is lower than its cost, the difference shall be recognized as a loss in earnings in the period in which it occurs. That loss may be required, for example, due to damage, physical deterioration, obsolescence, changes in price levels, or other causes [ASC 330-10-35-1B].

A departure from the cost basis of pricing inventory measured using LIFO or the retail inventory method is required when the utility of the goods is no longer as great as their cost. Where there is evidence that the utility of goods, in their disposal in the ordinary course of business, will be less than cost, whether due to damage, physical deterioration, obsolescence, changes in price levels, or other causes, the difference shall be recognized as a loss of the current period. This is generally accomplished by stating such goods at a lower level commonly designated as market [ASC 660-10-35-1C].

How should Company A assess if an impairment may exist? ↓



Solution


Company A would need to consider all available evidence to determine if there is an impairment. Suspending production and recalling the product are indicators that the carrying value of raw material inventory used to manufacture the drug as well as any related finished goods on hand may not be recoverable. Company A would need to evaluate the reason for the recall, its history with past recalls, the likelihood that the quality issue could be fixed, and if the raw materials have an alternative manufacturing use.

In addition to product recalls, the following events are impairment indicators within the pharmaceutical and life sciences industry:


- Patent expiration;
- Failure to meet regulatory or internal quality requirements;
- Product or material obsolescence;
- Market entrance of competitor products; and
- Changes or anticipated changes in third-party reimbursement policies that will impact the selling price of the inventory.

37. Accounting for patent-related costs

Background

 Company A has filed a number of patent applications and has incurred external legal and related costs in connection with the applications. Company A also has incurred legal costs in defense of its patents.

Relevant guidance

 Statement of Financial Accounting Concepts No. 6, paragraph 25, states “Assets are probable future economic benefits obtained or controlled by a particular entity as a result of past transactions or events.”

Statement of Financial Accounting Concepts No. 6, paragraph 247, states that “...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.”

AICPA Technical Practice Aids, Technical Questions and Answers Section 2260, states, “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.”

Should legal costs relating to the defense of pharmaceutical patents be capitalized? ↓



Solution

Determining whether to capitalize or expense patent application costs involves judgment. To capitalize patent application costs, there must be probable future economic benefit, otherwise, the costs would be expensed.

For example, if Company A has a product that is currently under research and development and is not currently approved for market, costs incurred in connection with patent application should generally be expensed in the income statement because there is uncertainty as to the future economic benefits of the asset. If a future economic benefit is probable or an alternate future use is available to the company, such costs can be capitalized and amortized over the expected life of the patent.

Company A can also capitalize external legal costs incurred in the defense of its patents when it is believed that the future economic benefit of the patent will be increased and a successful defense is probable. Capitalized patent defense costs are amortized over the remaining life of the related patent. Where the defense of the patent maintains rather than increases the expected future economic benefits from the patent, the costs would generally be expensed as incurred. Losses to defend allegations of infringement against other parties' patents are generally not in the defense of a company's own patents.



Sales and marketing


RECYCLABLE

38. Advertising and promotional expenditure – Scenario 1

Background



A pharmaceutical company has developed a new drug that simplifies the long-term treatment of kidney disease. The company's commercial department has incurred significant costs with a promotional campaign, including television commercials and presentations in conferences and seminars for doctors.

Relevant guidance



The costs of advertising... shall be expensed either as incurred or the first time the advertising takes place. The accounting policy selected from these two alternatives shall be applied consistently to similar kinds of advertising activities. Deferring the costs of advertising until the advertising takes place assumes that the costs have been incurred for advertising that will occur. Such costs shall be expensed immediately if such advertising is not expected to occur. Examples of the first time advertising takes place include the first public showing of a television commercial for its intended purpose and the first appearance of a magazine advertisement for its intended purpose [ASC 720-35-25-1].

Costs incurred to produce film or audio and video tape to be used to communicate advertising do not create tangible assets [ASC 720-35-25-2].

Costs of communicating advertising are not incurred until the item or service has been received and shall not be reported as expenses before the item or service has been received. For example, the costs of television airtime shall not be reported as advertising expense before the airtime is used [ASC 720-35-25-5].

How should these costs be accounted for and presented in the financial statements? ↓



Solution


The company should not recognize its advertising and promotional costs as an intangible asset, even though the expenditure incurred may provide future economic benefits.

Advertising and promotional costs should be included within sales and marketing expenses. Depending on the accounting policy it selected, the company should charge all promotional costs to the income statement as incurred or the first time the advertising takes place. The costs of television airtime and print media space shall not be expensed before the airtime and print media space are used, respectively.


The notes to the financial statements should disclose (1) the accounting policy selected from the two alternatives allowed for reporting advertising costs and (2) the amount charged to advertising expense for each income statement presented.

39. Advertising and promotional expenditure – Scenario 2

Background

 Company A recently completed a major study comparing its Alzheimer's drug to competing drugs. The results of the study were highly favorable and Company A has invested in a significant new marketing campaign in 20X7. The campaign will be launched at the January 20X8 International Alzheimer's Conference. Company A has also paid for direct-to-consumer television, which will appear in February 20X8. Related direct-to-consumer internet advertising will also begin in February 20X8, and will be paid based on when viewers “click-through” to its Alzheimer site.

Relevant guidance

 The costs of advertising... shall be expensed either as incurred or the first time the advertising takes place. Deferring the costs of advertising until the advertising takes place assumes that the costs have been incurred for advertising that will occur. Such costs shall be expensed immediately if such advertising is not expected to occur. Examples of the first time advertising takes place include the first public showing of a television commercial for its intended purpose and the first appearance of a magazine advertisement for its intended purpose [ASC 720-35-25-1].

Costs of communicating advertising are not incurred until the item or service has been received and shall not be reported as expenses before the item or service has been received. For example, the costs of television airtime shall not be reported as advertising expense before the airtime is used [ASC 720-35-25-5].

The costs of direct-response advertising shall be capitalized if both of the following conditions are met: (1) the primary purpose of the advertising is to elicit sales to customers who could be shown to have responded specifically to the advertising and (2) the direct-response advertising results in probable economic benefits [ASC 340-20-25-4].

39. Advertising and promotional expenditure – Scenario 2 (continued)

How should expenditures on advertising and promotional campaigns be accounted for and presented in the 20X7 financial statements (i.e., before the campaign is launched)? ↓



Solution

Other than direct-response advertising and promotional expenditures (i.e., all costs to develop and produce the marketing campaign and related materials, including the television and internet advertisements) should be treated as an expense when incurred or the first time the advertisement takes place, depending on the Company's accounting policy election. Amounts paid to television broadcast providers in 20X7 should be accounted for as a prepayment in 20X7 and expensed when the advertisement airs in 20X8.

Although pay-per-click advertising could be indicative of direct-response advertising, Company A determined that the internet advertising component of the campaign would not meet the criteria for direct-response advertising. In making this determination, it considered that other significant efforts would be needed to elicit a sale of their Alzheimer drug beyond the internet advertisement itself. Specifically, such efforts would include the need for the prospective customer to schedule an appointment with a physician to determine if the product is right for them and ultimately have the drug prescribed to them. Therefore, costs for hits to Company A's internet site should be expensed based on the click-through rate in 20X7.

The notes to the financial statements shall disclose all of the following in relation to this scenario: (1) the accounting policy selected in expensing costs as incurred or the first time the advertising takes place, (2) the total amount charged to advertising expense for each income statement presented, with separate disclosure of amounts, if any, representing a write-down to net realizable value, and (3) the total amount of advertising reported as assets, if any, in each balance sheet presented.

40. Presentation of co-marketing income and expense

Background



Company A and Company B have entered into a co-marketing agreement for compound XY.

Company A will manufacture the product and sell it to Company B at cost plus a normal manufacturing margin. Company B decides to whom the product is sold, sets pricing in the region, and cannot return unsold product to Company A. Company B will also pay Company A 20% of its net sales of compound XY and will share a portion of any potential product liability. The promotion and commercialization of drugs are Company B's main operating activities.

How should Company A and Company B present co-marketing income and expense?↓



Solution

Company A

Company A should present 100% of the sales of compound XY to Company B as sales revenue, and the corresponding costs of production as a cost of goods sold.

Company A should consider presenting the co-marketing income (20% of Company B's sales to third parties) as a separate revenue caption on the income statement, if material.

Company B

Company B should present the payments received from customers as sales revenue, and the cost of purchasing compound XY from Company A as inventory and then cost of goods sold.

The 20% co-marketing expenditures paid to Company A are likely to be presented in Company B's accounts as selling and distribution expenses. If they are a material element of the respective cost, they should be separately identified as co-marketing expenses.

Refer to the implementation examples within ASC 808 for additional guidance.

Relevant guidance



A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two (or more) parties who are both active participants in the activity and exposed to significant risks and rewards dependent on the commercial success of the activity [ASC 808-10-20].

Participants in a collaborative arrangement shall report costs incurred and revenue generated from transactions with *third parties* (that is, parties that do not participate in the arrangement) in each entity's respective income statement pursuant to the guidance on principal versus agent considerations in paragraphs 606-10-55-36 through 55-40 [ASC 808-10-45-1].

For costs incurred and revenue generated from third parties, the participant in a collaborative arrangement that is deemed to be the principal for a given transaction under paragraphs 606-10-55-36 through 55-40 shall record that transaction on a gross basis in its financial statements [ASC 808-10-45-2].



Healthcare reform



41. Accounting for the annual pharmaceutical manufacturers fee

Background



The Patient Protection and Affordable Care Act, which was signed into law in the US in 2010, imposes an annual fee on pharmaceutical companies that manufacture or import branded prescription drugs for each calendar year beginning January 1, 2011. The determination of an entity's relative portion of the fee is based on the entity's branded prescription drug sales for the current year as a percentage of the industry's branded prescription drug sales for the same year.

Relevant guidance



The liability related to the annual fee shall be estimated and recorded in full upon the first qualifying sale for pharmaceutical manufacturers in the applicable calendar year in which the fee is payable with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable [ASC 720-50-25-1].

The annual fee shall be presented as an operating expense [ASC 720-50-45-1].

How should a company account for its allocation of the annual fee in its financial statements? ↓



Solution

In 2014, the Internal Revenue Service issued final regulations clarifying that a company incurs a liability for the annual fee in the period in which the underlying sales occur.

Because the annual fee is determined based on a company's market share in that year, the fee will need to be estimated for purposes of making the ongoing accrual. In this regard, it is important to consider whether there could be significant changes to a company's market share from one year to the next. This might be the case, for example, if the company has a branded product coming off patent which would reduce their market share. Alternatively, if a competitor has a "blockbuster" drug coming off patent, a company might project an increase in market share.


Companies must also reflect this cost as an operating expense.

A photograph of a patient in a light blue hospital gown lying in a bed. The patient's hands are resting on a medical device, possibly a ventilator or a similar piece of equipment. A person wearing white gloves is adjusting the device. The device has several tubes and connectors, some with colored caps (yellow, green, red). The background is a plain, light-colored wall.

Business combinations and asset acquisitions


42. Asset acquisition versus business combination

Background

 Company A owns the rights to several drug compound candidates that are currently in Phase I of development. Company A's activities primarily consist of research and development (R&D) that is being performed on the early stage drug compound candidates. Company A employs management and administrative personnel as well as scientists who are vital to performing the R&D.

Company B acquires the rights to the drug compound candidates along with the scientists formerly employed by Company A who are developing the acquired Phase I drug compound candidates. None of the acquired drug compounds are similar and two of the compounds are the predominant assets being acquired through this transaction.

Relevant guidance

 **Current guidance:** ASC 805-10-20 indicates that a business is an integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return. This definition of a business can result in a broad range of transactions qualifying as business acquisitions.

Businesses consist of assets/resources, and systems, standards, or protocols applied to those assets/resources, that have the ability to create economic benefits.

Additionally, as noted in ASC 805-10-55-5, to be considered a business, not all of the inputs and associated processes used by the seller need to be transferred, as long as a market participant is capable of continuing to manage the acquired group to provide a return (e.g., the buyer would be able to integrate the acquired group with its own inputs and processes) or readily obtain those inputs and processes.

Revised guidance:

ASC 805-10-55-3A defines a business as an integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants. Further, to be capable of this, a business must have, at a minimum, an input and a substantive process that together significantly contribute to the ability to create an output.

ASC 805-10-55-5A through 55-5C introduce a screen test to be performed by companies prior to performing a full assessment. The screen test states that if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the set is not considered a business.

If the screen test is not met, then a company must perform further assessment. The framework for this assessment is discussed in ASC 805-10-55-5D through 55-6 and SC 805-10-55-8 through 55-9.

42. Asset acquisition versus business combination (continued)

Should Company B account for the transaction as a business combination or an asset acquisition? ↓



Solution

Current guidance:

Company B should consider the stage of development of the drug compound candidates in determining whether a business has been acquired. In most cases, there are likely to be more processes associated with later stage drug compounds than those in earlier stages. However, a transaction involving the acquisition of drug compound candidates in early stage development can still be a business combination.

Company B acquired the Phase I drug compounds, along with the scientists who are vital to performing the R&D. The scientists have the necessary skills and experience and provide the necessary processes (through their skills and experience) that are capable of being applied to inputs to create outputs.

While Company B did not acquire a manufacturing facility, testing and development equipment, or a sales force, it determined that the likely market participants are other pharmaceutical companies that already have these items or could easily replicate them.

These factors would likely lead Company B to account for this acquisition as a business combination.

Revised guidance:

The screen test discussed in ASC 805-10-55-5A through 55-5C is the first step that Company B should perform in its assessment. In performing the screen test, Company B should consider whether substantially all of the purchase price fair value is concentrated in a single identifiable asset or a group of similar identifiable assets. Because Company B has acquired the rights to multiple drug compounds, the company should consider the nature of what is acquired, for example, phase of development, disease/indication, market segment, etc. Generally, based on the facts that none of the acquired compounds are similar and two of the compounds are the predominant assets being acquired through this transaction, the screen is likely not met.

If Company B does not meet the screen test, a full assessment must be performed, and instead it should consider whether it has acquired inputs, substantive processes, and outputs. Company B would likely conclude that there are no outputs acquired because the compounds are in early stage of development. As a result, ASC 805-10-55-5D states that the input and processes would only be able to significantly contribute to the ability to create outputs if there are employees that form an organized workforce. Company B would need to carefully consider whether the scientists hired by Company B through the transaction would meet the definition of an organized workforce that can be combined with an input and process to convert or develop an output. Factors to consider may include: the employees' roles, whether the workforce is subject to contracts with employers or service organizations, as well as the nature and stage of the assets acquired.

In the above fact pattern, a conclusion that an organized workforce was acquired would result in Company B acquiring a business as opposed to an asset.

43. Accounting for acquired in-process research and development (“IPR&D”)

Background



Company A is in the pharmaceutical industry and owns the rights to several product (drug compound) candidates. Company A’s activities only consist of research and development performed on these product candidates.

Company B, also in the pharmaceutical industry, acquires Company A, including the rights to all of Company A’s product candidates, testing and development equipment, and hires all of the scientists formerly employed by Company A, who are integral to developing the acquired product candidates. Company A also had a product candidate that received FDA approval, but for which it had not yet started production at the time of acquisition by Company B. Company B accounts for this transaction as an acquisition of a business.

How should Company B account for the acquired IPR&D? ↓



Solution

Company B will measure the acquired IPR&D at its acquisition date fair value and record it as an indefinite-lived IPR&D intangible asset. Subsequent to the acquisition, the acquired IPR&D would be tested for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. To do so, Company B may elect to perform a qualitative impairment assessment under ASC 350-30-35-18A. If the qualitative assessment either failed or was not used, Company B would then need to perform a quantitative assessment comparing the fair value of the IPR&D asset to its carrying value.

Incremental research and development costs subsequent to the acquisition would be expensed. Once the IPR&D asset becomes available for use, it should be amortized over its estimated useful life.

With regard to Company A’s product candidate that received FDA approval, any such completed product development (i.e., no longer “in-process”) would be recognized as a finite-lived intangible asset at the date of acquisition, separate from the acquired IPR&D, and amortized over its estimated useful life. The production, testing and developing equipment would generally be separately recognized as tangible assets, measured at fair value, and depreciated over their estimated useful lives.

Relevant guidance




Under ASC 805, acquired IPR&D continues to be measured at its acquisition date fair value but is accounted for initially as an indefinite-lived intangible asset (i.e., not subject to amortization).

Post-acquisition, acquired IPR&D is subject to impairment testing, as required by ASC 350-30-35, until the completion or abandonment of the associated research and development efforts. If abandoned, the carrying value of the IPR&D asset is written off. Once the associated research and development efforts are completed, the carrying value of the acquired IPR&D is reclassified as a finite-lived asset and is amortized over its useful life.


The requirement to recognize acquired IPR&D in an acquisition as an indefinite-lived intangible asset does not apply to incremental costs incurred on the IPR&D project after the acquisition date. These incremental costs, unless there is an alternative future use, continue to be expensed as incurred under ASC 730-10-25.

44. Unit of account – IPR&D

Background

 Company A acquires Company B, a small pharma company, in a transaction accounted for as an acquisition of a business under ASC 805. Company B is developing a drug compound that is expected to become a leading product for its therapeutic indication. The project reached market approval in Canada, USA, and Europe just prior to acquisition, and regulatory approval is currently being pursued in Japan and Brazil. The project has been scaled to allow for additional trials to meet the regulatory requirements in each future jurisdiction.

Relevant guidance

 Under ASC 805, because of the requirement to capitalize and test the acquired IPR&D asset for impairment, it is important to determine the appropriate unit of account. Reference should be made to ASC 350-30-35 for factors to consider in determining the appropriate unit of accounting both for recognition and subsequent impairment assessments. This determination for valuing and recognizing acquired IPR&D can be complex when an approved drug may ultimately benefit various jurisdictions. One common approach is to record separate jurisdictional assets for a research and development activity that will benefit various jurisdictions, while another approach is to record a single global asset. When making the unit of account determination, companies may consider, among other things, the following factors:

- Phase of development of the related IPR&D project(s);
- Nature of the activities and costs necessary to further develop the related IPR&D project(s);
- Risks associated with the further development of the related IPR&D project(s);
- Amount and timing of benefits expected to be derived from the developed asset(s);
- Expected economic life of the developed asset(s);
- Whether there is an intent to manage advertising and selling costs for the developed asset(s) separately or on a combined basis; and
- Once completed, whether the product would be transferred as a single asset or multiple assets.

What is the unit of account for the acquired IPR&D asset? ↓




Solution

It depends. Industry practice would suggest that Company A may recognize at least two, and potentially up to five, separate assets: intangible assets representing the rights to the compound in each of the market-approved jurisdictions (or a single asset that includes rights for all market approved jurisdictions if they can be aggregated as discussed above) and one IPR&D asset for the portion still being developed (or two if separated by jurisdiction). The late stage of development combined with the plan to scale trials to meet regulatory requirements in each future jurisdiction may suggest that further disaggregation of the intellectual property still being developed is warranted. However, the specific facts and circumstances would need to be assessed to determine if the cost and risk profiles would be different.


45. Amortization of acquired intellectual property

Background

 Company A acquires Company B in a business combination accounted for under ASC 805. As part of the business combination, Company A acquires the intellectual property of Company B that meets the contractual-legal criterion for separate recognition of an intangible asset apart from goodwill. The intellectual property acquired by Company A does not represent IPR&D.

When should Company A begin amortizing acquired intellectual property, over what period, and how should the costs be classified in the income statement? ↓

Relevant guidance

 Pursuant to ASC 805, an intangible asset that meets the contractual-legal criterion or separability criterion is considered identifiable and is recognized at fair value using the market participant framework contained in ASC 820, *Fair Value Measurements and Disclosures*. Intangible assets are amortized over their estimated useful lives. If the precise length is unknown, intangible assets should be amortized over a company's best estimate of the assets' useful life. In determining the useful lives of intangible assets, companies should consider ASC 350-30-35-2 through 35-4.

Further, the classification of amortization expense should generally be determined based on the asset's intended use and recorded in the income statement accordingly.



Solution

Amortization of intangible assets should begin at the acquisition date, which is generally the date the asset is available for its intended use.

ASC 350-30-35-2 states that the useful life of an intangible asset to an entity is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of that entity. In addition, ASC 350-30-35-3 indicates that the estimate of an intangible asset's useful life should be based on all pertinent factors and prescribes the following factors that an entity should consider when estimating the useful life of an intangible asset:

- a. The expected use of the asset by the entity.
- b. The expected useful life of another asset or a group of assets to which the useful life of the intangible asset may relate.
- c. Any legal, regulatory, or contractual provisions that may limit the useful life. The cash flows and useful lives of intangible assets that are based on legal rights are constrained by the duration of those legal rights. Thus, the useful lives of such intangible assets cannot exceed the length of their legal rights and may be shorter.
- d. The entity's own historical experience in renewing or extending similar arrangements, consistent with the intended use of the asset by the entity, regardless of whether those arrangements have explicit renewal or extension provisions. In the absence of that experience, the entity shall consider the assumptions that market participants would use about renewal or extension, consistent with the highest and best use of the asset by market participants, adjusted for entity-specific factors in this paragraph.
- e. The effects of obsolescence, demand, competition, and other economic factors (such as the stability of the industry, known technical advances, legislative action that results in an uncertainty or changing regulatory environment, and expected changes in distribution channels).
- f. The level of maintenance expenditures required to obtain the expected future economic benefits from the asset (for example, a material level of required maintenance in relation to the carrying amount of the asset may suggest a very limited useful life). As in determining the useful life of depreciable tangible assets, regular maintenance may be assumed but enhancements may not.

45. Amortization of acquired intellectual property (continued)



Solution

In addition to these factors, pharmaceutical and life sciences companies should consider industry-specific factors, such as the following:

- a. Duration of the patent right or license of the product;
- b. Redundancy of a similar medication/device due to changes in market preferences;
- c. Unfavorable court decisions on claims related to product liability or patent ownership;
- d. Regulatory decisions over patent rights or licenses;
- e. Development of new drugs treating the same disease;
- f. Changes in the environment that make the product ineffective (e.g., a mutation in the virus that is causing a disease, which renders it stronger);
- g. Changes or anticipated changes in participation rates or reimbursement policies of insurance companies; and
- h. Changes in government reimbursement or policies (e.g., Medicare, Medicaid) for drugs and other medical products.

If an income approach is used to measure the fair value of an intangible asset, then in determining the useful life of the intangible asset for amortization purposes, an entity shall consider the period of expected cash flows used to measure the fair value of the intangible asset adjusted as appropriate for the entity-specific factors noted above.

None of the above factors should be considered more presumptive than any other, and companies should consider all the facts and circumstances when estimating an asset's useful life. Companies should also evaluate the remaining useful lives of their intangible assets each reporting period to determine whether events and circumstances warrant revisions to the estimated useful lives. A change in the estimated useful lives of intangible assets is considered a change in an accounting estimate and should be accounted for prospectively in the period of change and future periods.

Income statement classification of an intangible asset's amortization expense should reflect the nature of the asset. If the technology supports the commercialization process or is utilized to manufacture goods, the presumption is that amortization should be recorded as part of cost of goods sold.

46. Cash flow presentation of up-front licensing fees

Background



Company A and Company B enter into an agreement in which Company A will license Company B's know-how and technology related to a compound in the research stage. The agreement stipulates that Company A will make a non-refundable payment of \$3 million to Company B for access to the technology.

Company A determines that this meets the definition of an asset acquisition and the license has no alternative future use. Company A expenses the \$3 million as incurred as research and development costs.

What is the appropriate presentation of up-front licensing fees on the statement of cash flows? ↓

Relevant guidance



Under ASC 230-10-45-10, "A statement of cash flows shall classify cash receipts and cash payments resulting from investing, financing, or operating activities" using the definitions of these terms in ASC 230-10-20.



Solution

Company A should consider the nature of the underlying cash flow in determining its classification. Given that the nature of this cash flow has aspects of more than one class of cash flows, Company A should classify this use of cash based on what is likely to be the predominant use of cash flows for the item. In the case of an upfront license fee that has been expensed and does not appear on the statement of financial position, the predominant class of cash flows would generally be an operating activity.



*Revenue recognition
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47. Assessing distinct promises (license and R&D services)

Background



Company A, a biotechnology company, enters into an arrangement to provide Company B with a license to manufacture and commercialize an early-stage drug compound as well as perform ongoing research and development services to continue to develop the compound. The compound is currently in Phase II clinical trials. The license is delivered to Company B in the first quarter and the research and development services will be provided over a two year period.

Relevant guidance



ASC 606-10-25 indicates that a good or service that is promised to a customer is distinct if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer.
- The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

A customer can benefit from a good or service if it can be used, consumed or sold (for an amount greater than scrap value) to generate economic benefits.

Factors that indicate the promise is separately identifiable include:

- The entity is not using the good or service as an input to produce or deliver a combined output.
- The good or service does not significantly modify or customize another good or service promised in the contract.
- The good or service is not highly dependent on, or highly interrelated with, other goods or services in the contract.

Further, ASC 606-10-55-56 provides the following examples of when a license is not distinct from other goods or services in an arrangement:

- A license that forms a component of a tangible good and that is integral to the functionality of the good.
- A license that the customer can benefit from only in conjunction with a related service.

47. Assessing distinct promises (license and R&D services) (continued)

What factors should Company A consider when assessing whether the license is a distinct performance obligation in this arrangement? ↓



Solution

Significant judgment is required when identifying the number of performance obligations in an arrangement that includes a license to IP as well as R&D services performed by the licensor. In determining whether the license is distinct, Company A should consider whether the license is capable of being distinct and whether the promise to transfer the license is distinct in the context of the contract.

Capable of being distinct

This criterion is met if Company B can benefit from the license on its own or with other readily available resources.

The license may not be capable of being distinct if the R&D services are so specialized that the services could only be performed by Company A as opposed to Company B or another qualified third party.

Distinct in the context of the contract

This criterion is met if the promise to transfer the license is separately identifiable from the R&D services.

The license may be separately identifiable from the R&D services if the R&D services are not expected to significantly modify or customize the initial IP. Such is the case for clinical trials where the purpose is to validate the usage and efficacy of a drug versus significantly modifying or customizing the initial IP (e.g., the drug compound).

Conversely, in the case of very early stage IP (e.g., within the drug discovery cycle) whereby the R&D services are expected to involve significant further development of the drug formula or biological compound, Company A might conclude that the license is not separately identifiable from the R&D services.

Company A should also evaluate if the R&D services are optional; that is, the customer could decide to cancel at any time with no penalty or hire another vendor or biotech to perform the services. Optional services may indicate that the only enforceable rights and obligations relate to the license of IP. However, Company A would need to assess in this instance if a material right exists with regard to future optional R&D services (e.g., if the R&D services were priced at an amount below standalone selling price).

48. Assessing distinct promises (license and manufacturing)

Background



Company A, a pharmaceutical company, enters into an agreement with Company B to provide them with a license related to a mature product for a period of 10 years. For the first 5 years, Company A will continue to manufacture the drug while Company B is developing their manufacturing facilities in order to continue to manufacture the product. As the license is related to a mature product, it is not expected that the underlying product will change over the license period.

Relevant guidance



ASC 606-10-25 indicates that a good or service that is promised to a customer is distinct if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer.
- The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

A customer can benefit from a good or service if it can be used, consumed or sold (for an amount greater than scrap value) to generate economic benefits.

Factors that indicate the promise is separately identifiable include:

- The entity is not using the good or service as an input to produce or deliver a combined output.
- The good or service does not significantly modify or customize another good or service promised in the contract.
- The good or service is not highly dependent on, or highly interrelated with, other goods or services in the contract.

Further, ASC 606-10-55-56 provides the following examples of when a license is not distinct from other goods or services in an arrangement:

- A license that forms a component of a tangible good and that is integral to the functionality of the good.
- A license that the customer can benefit from only in conjunction with a related service.

48. Assessing distinct promises (license and manufacturing) (continued)

What factors should Company A consider when assessing whether the license is a distinct performance obligation in this arrangement? ↓



Solution

Determining whether the license is distinct in this scenario will depend upon the facts and circumstances surrounding the license and the related manufacturing services. Company A will need to determine whether the customer can benefit from the license on its own, as well as whether the license is separately identifiable from the manufacturing services.

For example, if the manufacturing process is highly specialized and only Company A has the knowledge and expertise to perform the manufacturing services, the license may not be distinct as the customer cannot benefit from the license on its own but rather requires the ongoing involvement of Company A to continue the manufacturing. In this instance, the license may not be separately identifiable as Company B has not contracted with Company A for only the license, but for the combined output of the license as well as the manufacturing of the product for the first 5 years. In other words, the customer can benefit from the license only in conjunction with the related manufacturing services and therefore the license is not considered distinct.

Conversely, if Company B could contract with another company to perform the manufacturing services, the license may be distinct as the customer can benefit from the license on its own without Company A's ongoing involvement. This would be the case even if Company B is contractually required to use Company A to manufacture the product for the defined period. Additionally, the license may be separately identifiable as Company B is not contracting for the combined output of the license and manufacture of product, and Company A could fulfill its promise to deliver the license independent of fulfilling the promise to provide manufacturing services. In this instance, the entity may be able to conclude that the license is a distinct performance obligation.

Refer to ASC 606 Example 56 – *Identifying a distinct license* for additional guidance on this topic.

49. Determining standalone selling price

Background



Company A enters into an arrangement that includes the sale of a license along with ongoing research and development services for one fixed price. The license is delivered to the customer in the first quarter, and the R&D services will be provided over a three year period. Company A has assessed the nature of the arrangement and determined that both the license and R&D services are distinct performance obligations and therefore Company A needs to allocate the total transaction price between the license and the R&D services. In the past, the Company has not sold either the license or R&D services individually.

Relevant guidance



In accordance with ASC 606-10-32, to allocate the transaction price to each performance obligation on a relative standalone selling price basis, an entity shall determine the standalone selling price at contract inception of the distinct good or service underlying each performance obligation in the contract and allocate the transaction price in proportion to those standalone selling prices.

The best evidence of standalone selling price is the price an entity charges for that good or service when the entity sells it separately in similar circumstances to similar customers. The standalone selling price needs to be estimated or derived by other means if the good or service is not sold separately.

49. Determining standalone selling price (continued)

How would Company A determine the standalone selling price of each performance obligation in the arrangement in order to allocate consideration among them? ↓



Solution

In the example above, the standalone selling price is not directly observable as Company A does not sell the license or R&D services on a standalone basis. Therefore, Company A will need to estimate the standalone selling price of each performance obligation in order to allocate the transaction price in this arrangement.

Under ASC 606, there is not a particular estimation method that is prescribed nor prohibited as long as the method results in an estimate that fairly represents the price the entity may charge for the goods or services if they were sold separately. Additionally, there is not a prescribed hierarchy to be used in order to determine the standalone selling price; however, the entity should maximize the use of observable inputs in determining the estimated standalone selling price.

Company A may consider using the following methods to estimate the standalone selling price of each performance obligation:

- **Adjusted market assessment approach** - A market assessment approach considers the market in which the good or service is sold and estimates the price that a customer in that market would be willing to pay. This approach would consider competitor's pricing for similar goods or services adjusted for specific factors such as position in the market, expected profit margin and customer or geographic segments. In this example, Company A would need to also consider the exact rights associated with the license, the stage of development of the underlying product and the projected cash flows over the license period. Related to the R&D services, Company A may consider prices of similar services offered in the marketplace.
- **Expected cost plus a margin** - Under this method, an entity estimates the standalone selling price by considering the costs incurred to produce the product or service plus an adjustment for the expected margin expected on the sale. This method may be more appropriate if the license is in an early stage of development or forecasted revenues and cash flows do not exist. This method may also be appropriate in determining the selling price of R&D services by considering the level of effort necessary to perform the services.
- **Residual approach** - In limited circumstances, the residual approach may be used in order to determine the estimated standalone selling price of a good or service. This approach may only be used if the entity sells the same good or service to different customers for a broad range of amounts OR the entity has not yet established a price for that good or service and the good or service has not previously been sold on a standalone basis. Under this approach, the estimated standalone selling price of other goods and services in the contract are deducted from the total transaction price in order to determine the standalone selling price for the remaining goods and services.

Company A should use judgement in order to determine which method will best estimate the price that would be paid if the license and services were sold on a standalone basis.

50. Accounting for options

Background



Company A enters into an arrangement to provide Company B with a license to use its intellectual property for a single indication.

Company A also provides Company B with an option during the term of the arrangement to obtain additional indications if the intellectual property is proven effective for any other indications.

How should Company A evaluate the option it provided to Company B? ↓

Relevant guidance



If, in a contract, an entity grants a customer the option to acquire additional goods or services, that option gives rise to a performance obligation in the contract only if the option provides a material right to the customer that it would not receive without entering into that contract (for example, a discount that is incremental to the range of discounts typically given for those goods or services to that class of customer in that geographical area or market). If the option provides a material right to the customer, the customer in effect pays the entity in advance for future goods or services, and the entity recognizes revenue when those future goods or services are transferred or when the option expires [ASC 606-10-55-42].

If a customer has a material right to acquire future goods or services and those goods or services are similar to the original goods or services in the contract and are provided in accordance with the terms of the original contract, then an entity may, as a practical alternative to estimating the standalone selling price of the option, allocate the transaction price to the optional goods or services by reference to the goods or services expected to be provided and the corresponding expected consideration [ASC 606-10-55-45].



Solution

Company A should consider whether the option provided to Company B offers a future discount that is incremental to the range of discounts typically given to the same class of customer.

If the option provides a material right to Company B, there are two performance obligations in the arrangement: the license to use Company A's intellectual property for a single indication and the right to licenses for additional indications in the future. In this scenario, Company A would need to allocate a portion of the transaction price to both the current license and the right to future licenses based on the standalone selling price of each performance obligation. If the standalone selling price for Company B's option is not directly observable, Company A should estimate it. That estimate should reflect the discount that Company B would obtain when exercising the option, adjusted for (1) any discount that Company B could receive without exercising the option and (2) the likelihood that the option will be exercised. The amount allocated to the material right would be recognized when the future licenses transfer to Company B or when the option expires.

If the option to obtain additional licenses are at a price that reflects the standalone selling price for the additional license, the option does not provide Company B with a material right even if the option can only be exercised by entering into a previous contract. In this scenario, Company A should account for the option only when Company B exercises the option to purchase the additional future licenses.

51. Price protection

Background



Company A, a pharmaceutical drug manufacturer, enters into a sales arrangement with a group purchasing organization (GPO).

Included in the agreement is a price protection clause that guarantees that the GPO will receive Company A's lowest selling price. If Company A sells its products to another customer at a lower price, the GPO will receive the lower price on all future purchases. Company A does not have any history of providing retroactive price adjustments to its customers.

Relevant guidance



If, in a contract, an entity grants a customer the option to acquire additional goods or services, that option gives rise to a performance obligation in the contract only if the option provides a material right to the customer that it would not receive without entering into that contract (for example, a discount that is incremental to the range of discounts typically given for those goods or services to that class of customer in that geographical area or market). If the option provides a material right to the customer, the customer in effect pays the entity in advance for future goods or services, and the entity recognizes revenue when those future goods or services are transferred or when the option expires [ASC 606-10-55-42].

Does inclusion of this price protection clause impact the current sales to the GPO? ↓



Solution

It depends. Company A will need to assess whether it has conveyed a material right to the GPO to buy products at a lower price in the future. In this case, it does not appear to be a material right as the lowest price guarantee only applies to future purchases by the GPO and is not based on cumulative past purchases by the GPO (i.e., volume discount).

If Company A concludes that a material right does not exist, there is no accounting impact on the current sales, and future sales will be accounted for at the relevant prices.

In this determination, Company A would consider, among other things, whether the right is incremental to those received by other similar classes of customers in the same market.

If Company A concludes a material right exists, this would be a separate performance obligation and a portion of the transaction price would need to be allocated to the material right. The entity will recognize revenue allocated to the material right associated with the optional purchases when the additional goods and services are transferred to the customer or when the option expires.

52. Determine the transaction price

Background



Company A, a biotechnology company, enters into a license arrangement with Company B, a pharmaceutical company, to jointly develop a potential drug that is currently in Phase II clinical trials. As part of the arrangement, Company A agrees to provide Company B a perpetual license to Company A's proprietary intellectual property. Company A also agrees to provide research and development services in the form of clinical trials to Company B to develop the potential drug. Company A determines that the arrangement consists of two performance obligations.

Company A receives an upfront payment of \$20 million at the inception of the arrangement and is eligible to receive a milestone payment of \$25 million upon regulatory approval.

How should Company A determine the transaction price for this arrangement? ↓



Solution

Company A will receive a fixed amount of \$20 million upfront and may receive a variable amount of \$25 million based on the contingent milestone. In this case, Company A uses the most likely amount method since the outcome is binary (i.e., either regulatory approval is granted or it is not).

At contract inception, Company A may not be able to assert that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. This conclusion is based on the current stage of development and the fact that regulatory approval (i.e., judgments and actions of third parties) cause the underlying consideration to be highly susceptible to factors outside of the company's influence.

Therefore, at contract inception, Company A estimates a total transaction price of \$20 million, consisting of the upfront payment only. The transaction price is allocated to the two performance obligations on a relative stand-alone selling price basis, and revenue is recognized as each performance obligation is satisfied. As facts and circumstances change during the performance period, Company A may be able to overcome the constraint and include in the transaction price the anticipated milestone payment once it becomes probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved.

Relevant guidance



ASC 606-10-32-2 indicates that an entity shall consider the terms of the contract and its customary business practices to determine the transaction price. The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.

An entity shall estimate an amount of variable consideration via the expected value or most likely amount method, depending on which method the entity expects to better predict the amount of consideration to which it will be entitled [ASC 606-10-32-8].

An entity shall include in the transaction price some or all of an amount of variable consideration estimated in accordance with paragraph 606-10-32-8 only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved [ASC 606-10-32-11].

53. Right of return

Background



Company A sells cardiac drugs through a number of wholesale and retail customers. The drugs have a shelf life of 24 months from the date manufactured. Both wholesalers and retailers can return the drugs from six months before to six months after the expiration date, subject to compliance with other provisions in Company A's returns policy.

Company A has sold these drugs for the past two years. Through December 31, 20X6, 3% of the drugs have been returned in accordance with policy.

On December 31, 20X6, Company A delivered 100 units to Distributor Z for \$200 each, for a total sale of \$20,000.

Can Company A recognize the full \$20,000 as revenue on December 31, 20X6? ↓

Relevant guidance



ASC 606-10-55-22 to 55-29, Revenue from Contracts with Customers, specifies the accounting when an entity transfers control of a product to a customer and also grants the right to return the product for various reasons and receive any combination of the following:

- A full or partial refund of any consideration paid.
- A credit that can be applied against amounts owed, or that will be owed, to the entity.
- Another product in exchange.

To account for the transfer of products with the right of return, an entity should recognize the following:

- Revenue for the transferred products in the amount of consideration to which the entity expects to be entitled (therefore, revenue would not be recognized for products expected to be returned).
- A refund liability.
- An asset (and corresponding adjustment to cost of sales) for its right to recover products from customers on settling the refund liability.

An entity should apply the guidance in paragraphs 606-10-32-2 through 32-27 (including the guidance on constraining estimates of variable consideration in paragraphs 606-10-32-11 through 32-13) to determine the amount of consideration to which the entity expects to be entitled (that is, excluding the products expected to be returned).



Solution

No. Company A should not recognize the full \$20,000 as revenue at December 31, 20X6.

Company A will need to utilize judgment in determining the exact amount of revenue to recognize at that date. Company A will first need to determine the level of sales for which it is probable there will be no significant revenue reversal due to product returns. Company A will need to analyze its return volume, return patterns, current demand levels, the level of inventory currently in the distribution channel and any new or upcoming Company A or competitor products that may render the product obsolete or otherwise impact product demand. Company A will need to determine if there is a minimum level of sales for which it is probable that a change in estimate of returns would not cause a significant reversal of revenue, and record revenue for these sales.

53. Right of return (continued)



Solution (continued)

Although Company A has sold the product for 2 years and has a history of returns experience, because of the extended nature of the return policy, it should assess whether the returns experience is sufficient in developing its returns estimate. If Company A determines it is probable there will not be a significant reversal of cumulative revenue recognized in the future, it should reduce the revenue recognized as of December 31, 20X6 by the amount of the estimated returns. For example, if Company A estimates a 3% return rate, it would recognize net revenue of \$19,400 (\$20,000 total order—(3% x \$20,000 product sales)) at December 31, 20X6, a refund liability of \$600 (3% x \$20,000 product sales), and an asset (and corresponding adjustment to cost of sales) for its right to recover products from customers on settling the refund liability. The asset would be measured at the carrying amount of goods at the time of the sale, net of any impairment for expected costs to recover the products or potential decreases in the value of returned products (e.g., due to the limited remaining shelf life of returned products).

54. Rebates to end users

Background



Company A enters into an arrangement with Retailer X for the sale of pharmaceutical drugs. Retailer X then sells the product to Customer B (the end user). Customer B is entitled to a sales rebate from Company A of 25% of the sales price of the first 100 units if 1,000 units are purchased.

Company A has developed a relationship with Customer B after selling pharmaceutical drugs for a number of years. Further, Company A has offered a similar sales arrangement to Customer B in prior years.

The unit selling price for each product is \$100. Company A believes that it has sufficient basis to estimate that the end customer will purchase the necessary 1,000 units during the year.

Relevant guidance



The accounting guidance for customer payments and incentives is included in ASC 606-10-32-25 through 32-27. This guidance indicates that rebates (either to a customer or to other parties that purchase the entity's goods or services from the customers) shall be accounted for as a reduction of the transaction price and, therefore, a reduction of revenue unless the payment to the customer is in exchange for a distinct good or service that the customer transfers to the entity.

ASC 606-10-32-25 provides guidance pertaining to variable amounts: if the consideration payable to a customer includes a variable amount, an entity shall estimate the transaction price (including assessing whether the estimate of variable consideration is constrained) in accordance with paragraphs 606-10-32-5 through 32-13.

How should Company A account for rebates to be paid to the end user? ↓



Solution


In this fact pattern the performance obligation in the contract is the promise to deliver individual units of the pharmaceutical drugs to the distributor as requested over the term of the sales arrangement. To determine the transaction price, Company A will need to estimate the effects of the rebates offered to the end user. Since Company A estimates that under this contract 1,000 units will be delivered to Customer B, the total rebate will be \$2,500 (i.e., 25% rebate x 100 units x \$100 price per unit). The total estimated rebate will be a reduction from the contractual sales price.

For determining the amount of rebate to recognize upon each product sale, Company A takes the full estimated rebate (\$2,500) and divides by the 1,000 units (Company A's expected sales). As each of the units are shipped, Company A would recognize a rebate accrual of 2.5% (\$2,500 total rebate/\$100,000 anticipated sales). The rebate would be accrued as an offset to revenue. Company A would record sales to the distributor at a transaction price of \$97.50 (\$100 less 2.5% discount). At the end of each quarter, Company A would revise the estimate of sales and true up the calculation and rebate that will be due at the end of the arrangement. This true up would include a cumulative adjustment on shipments through that date.

Even though the product was sold to a distributor and the rebates are paid to end users, the classification of the payment is still as a reduction of revenue under ASC 606-10-32-25 through 32-27.

55. Rebates on volume purchases

Background

 Company A has a multi-year contract with Company B to sell pharmaceutical drugs and agrees to pay Company B an annual rebate if Company B completes a specified cumulative level of purchases during any year of the contract period. The contract specifies that the amount of rebate will vary based on a tiered structure agreed to in the contract as follows (note that the rebate earned is not retroactive to prior purchases):

Purchases	Rebate	Probability
1-10 units	0%	15%
11-20 units	2%	60%
Greater than 21 units	5%	25%

The unit price for each product is \$100. Based on historical experience of rebates due to Company B, Company A has assigned probabilities to each possible outcome.

How should Company A account for the rebate expected to be paid to the customer at the end of the year?




Solution

In this case, Company A determines that the expected value method better predicts the amount of consideration to which it will be entitled. Company A concludes that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved.

Under the expected value approach, Company A estimates the rebate to be 2.45% ((0% rebate x 15% likelihood) + (2% rebate x 60% likelihood) + (5% rebate x 25% likelihood)), based on a probability-weighted assessment of each possible scenario. Therefore, as each unit is shipped, Company A will recognize a rebate accrual of \$2.45 and revenue of \$97.55 under this approach.

Relevant guidance


 Under contracts which provide rebates on volume purchases, the customer will typically pay the full price for the goods and then receive a cash rebate in the future. ASC 606-10-32-25 states that consideration payable to a customer should be accounted for as a reduction of the transaction price unless the payment to the customer is in exchange for a distinct good or service. The consideration payable to the customer is variable in these situations because it is based on the volume of eligible transactions.

An entity shall estimate an amount of variable consideration by using either of the following methods, depending on which method the entity expects to better predict the amount of consideration to which it will be entitled:

- The expected value—the expected value is the sum of probability-weighted amounts in a range of possible consideration amounts.
- The most likely amount—the most likely amount is the single most likely amount in a range of possible consideration amounts (that is, the single most likely outcome of the contract) [ASC 606-10-32-8].


56. Volume purchase arrangements

Background

 Company A enters into a two-year arrangement with Company B for the sale of pharmaceutical drugs on January 1, 20X2. The terms of the agreement do not specify any contractual minimum purchases by Company B. However, once the number of purchases exceeds 1,000 units of the drug, the price per unit decreases from \$12 per unit (which represents the “list” price for this drug) to \$8 per unit for each unit purchased thereafter (which is often referred to as a volume purchase arrangement).

On October 31, 20X2, Company B issues a purchase order for 1,000 units of the drug. As of December 31, 20X2, Company A forecasts that another 1,000 units will be sold, and on January 15, 20X3, Customer B issues a second purchase order for another 1,000 units of the drug. Based on its forecast, Company A does not expect Company B to issue any additional purchase orders under the two-year arrangement.

Relevant guidance

 Volume discount arrangements include variable consideration because the total amount to be paid by the customer is not known at contract inception and is affected by the amount of goods or services ultimately purchased.

Volume purchase arrangements affect the timing of revenue recognition if they provide the customer with a material right. As discussed in ASC 606-10-55-42, a material right to a discounted product in the future is a separate performance obligation to which a portion of the transaction price from current sales should be allocated. Revenue allocated to the right is recognized when the discounted goods are provided or the right expires. An entity needs to estimate the volume discounts it expects customers to earn based on experience with similar contracts to determine the portion of the transaction price to allocate to the right.

Per ASC 606-10-55-44, if the standalone selling price for a customer’s option to acquire additional goods or services is not directly observable, an entity should estimate it. The revenue standard does not prescribe or prohibit any particular method for estimating the standalone selling price, as long as the method results in an estimate that faithfully represents the price an entity would charge for the goods or services if they were sold separately. Suitable methods include, but are not limited to, the adjusted market assessment approach, expected cost plus margin approach and the residual approach.

A practical expedient is included in ASC 606-10-55-45 which states that if a customer has a material right to acquire future goods or services and those goods or services are similar to the original goods or services in the contract and are provided in accordance with the terms of the original contract, then an entity may allocate the transaction price to the optional goods or services by reference to the goods or services expected to be provided and the corresponding expected consideration.

56. Volume purchase arrangements (continued)

How should Company A account for the sale of the first 1,000 units of the drug?



Solution

Company A needs to evaluate whether the volume purchase arrangement represents a material right.

Company A offers Company B a 33.3% discount (\$4 discount off of the \$12 per unit price) on all purchases after the first 1,000 units. Assume that Company A routinely offers other similarly-sized customers a 5% discount (which yields a net price of \$11.40 per unit). Therefore, Company A determined that the volume purchase arrangement represents a material right provided to Company B. Company A must either calculate the value of the material right and allocate the total transaction price based on relative standalone selling prices or use the practical alternative.

Allocation based on relative standalone basis

Company A needs to determine the standalone selling price of the option to purchase additional units at the discounted price. This is calculated as:

Estimated purchase of additional products	\$12,000 (1,000 units x \$12)
Multiplied by: the incremental discount	x 28.3% (33.3% - 5% offered to other customers)
Multiplied by: the likelihood of exercise	x 100%
Standalone selling price of the option	\$3,400
Standalone selling price of 1,000 units	<u>\$11,400</u>
Combined stand-alone selling price	\$14,800

When Company A sells the first 1,000 units to Company B, it will receive \$12,000 (1,000 units x \$12). Company A would allocate \$2,757 (\$12,000 consideration X (\$3,400/\$14,800 total stand-alone selling price)) of the consideration to the material right (i.e., as a contract liability) and the remaining \$9,243 would be recognized as revenue. The transaction price allocated to the discount, based on the relative standalone selling price, will be recognized upon exercise (that is, purchase of additional product) or expiry.

When Company A sells the second 1,000 units to Company B, it will receive \$8,000 (1,000 units x \$8). Company A would recognize the \$8,000 received as well as the \$2,757 transaction price allocated to the discount. By purchasing the second 1,000 units, Company B has exercised its option to purchase products at the discounted price and Company A does not expect Company B to purchase any additional units under the contract. Accordingly, the full value allocated to the material right should be recognized.

Practical alternative (ASC 606-10-55-45)

As Company A has a sufficient basis to estimate that 2,000 units will be purchased, Company A could estimate the total consideration that Company B will pay under the volume purchase arrangement and divide that by the 2,000 units. The transaction price per unit on 2,000 units would be \$10 ((1,000 units x \$12 plus 1,000 units x \$8)/2,000 total units). As each unit is shipped, the Company would recognize revenue of \$10. At the end of each quarter, Company A would revise the estimate of sales under the volume purchase arrangement and record a true-up to reflect the cumulative adjustment on shipments through that date.

57. Free products

Background



Company A sells a drug to treat hypertension to Company B. In connection with the sale, Company A agrees to also provide a specific amount of a drug to treat high cholesterol for free.

Company A has established the selling prices for both drugs based on their individual separate sales. Both drugs each have value to Company B on a standalone basis.

How should Company A recognize the free drug provided to Company B? ↓

Relevant guidance



Per ASC 606-10-32-28, the objective when allocating the transaction price is for an entity to allocate the transaction price to each performance obligation in an amount that depicts the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services to the customer. Per ASC 606-10-32-31, to allocate the transaction price to each performance obligation on a relative standalone selling price basis, an entity should determine the standalone selling price at contract inception of the distinct good or service underlying each performance obligation in the contract and allocate the transaction price in proportion to those standalone selling prices.

As noted in ASC 606-10-32-32, the standalone selling price for a good or service may be the contractually stated price, but shall not be presumed to be. In this case, the ‘free’ price stated in the contract for a specified number of disposables is not considered to be the standalone selling price.




Solution

The transaction price should be allocated to each performance obligation based on the relative standalone selling prices of the goods being provided to the customer. Company A should allocate total consideration in this arrangement between the two drugs based on their relative standalone selling prices and recognize revenue for each performance obligation when all criteria in ASC 606 have been met.

58. Pay-for-performance arrangements


Background

 Company A manufactures, markets, and sells Drug B to a hospital. The hospital administers Drug B to its patients. Under the terms, if after a defined treatment period of three months, patients' test results do not meet the pre-determined objective criteria, the hospital is eligible for a full refund for the administered product from Company A. The hospital has two months after the treatment period to process the request for refund (i.e., a total of five months after the initial treatment).

Company A obtained Food and Drug Administration ("FDA") approval for Drug B two years ago, and began selling Drug B immediately to the hospital. Over the past two years, Company A and the hospital have been tracking the number of patients whose post-treatment test results did not meet the pre-determined criteria, and it has consistently ranged from 6–7% on a monthly and annual basis. Based on the nature of this drug as well as the relatively consistent patient results over the past two years, Company A expects future refunds to be consistent with historical results.

How should Company A account for this arrangement? ↓

Relevant guidance

 An entity shall include in the transaction price some or all of an amount of variable consideration, only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved [ASC 606-10-32-11].

Factors that could increase the likelihood or the magnitude of a revenue reversal include, but are not limited to, any of the following:

- a. The amount of consideration is highly susceptible to factors outside the entity's influence. Those factors may include volatility in a market, the judgment or actions of third parties, weather conditions, and a high risk of obsolescence of the promised good or service.
- a. The uncertainty about the amount of consideration is not expected to be resolved for a long period of time.
- b. The entity's experience (or other evidence) with similar types of contracts is limited, or that experience (or other evidence) has limited predictive value.
- c. The entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions of similar contracts in similar circumstances.
- d. The contract has a large number and broad range of possible consideration amounts.



Solution

Contingencies such as the one described above represent a form of variable consideration.

Company A needs to estimate the total transaction price at contract inception using either the expected value method or most likely amount method, whichever it deems to be most appropriate for this arrangement. Given historical experience and the expectation that future results will be comparable with that experience, Company A may conclude that it has the ability to predict the number of patients who will benefit from the drug. Therefore, Company A may include an amount of variable consideration in the transaction price that would not be subject to a significant revenue reversal when the uncertainty is subsequently resolved.

Conversely, Company A may conclude that, given potential differences in population between clinical trials (which established the pre-determined objective criteria) and this particular hospital, Company A cannot assert that it is probable that a significant reversal of revenue will not occur in the future. Therefore, Company A may fully constrain the transaction price initially as Company A's experience has limited predictive value.

59. Revenue recognition for customers with a history of long delays in payment

Background



Company A, a pharmaceutical company, sells prescription drugs to a governmental entity in a country in Europe. Company A has historically experienced long delays in payment for sales to this entity due to slow economic growth and high debt levels in the country. Company A currently has outstanding receivables from sales to this entity over the last three years and continues to sell product at its normal market price. The receivables are non-interest bearing.

Relevant guidance



ASC 606-10-25-1 states that an entity shall account for a contract with a customer that is within the scope of this Topic only when all of the following criteria are met... it is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer. In evaluating whether collectability of an amount of consideration is probable, an entity shall consider only the customer's ability and intention to pay that amount of consideration when it is due. The amount of consideration to which the entity will be entitled may be less than the price stated in the contract if the consideration is variable because the entity may offer the customer a price concession.

ASC 606-10-32-11 states that an entity shall include in the transaction price some or all of an amount of variable consideration...only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

ASC 606-10-32-15 states that in determining the transaction price, an entity shall adjust the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer or the entity with a significant benefit of financing the transfer of goods or services to the customer. In those circumstances, the contract contains a significant financing component. A significant financing component may exist regardless of whether the promise of financing is explicitly stated in the contract or implied by the payment terms agreed to by the parties to the contract. Furthermore, ASC 606-10-32-18 provides a practical expedient that an entity need not adjust the promised amount of consideration for the effects of a significant financing component if the entity expects, at contract inception, that the period between when the entity transfers a promised good or service to the customer and when the customer pays for that good or service will be one year or less.

59. Revenue recognition for customers with a history of long delays in payment (continued)

How should Company A account for the outstanding receivables and future sales to the governmental entity in this country in Europe? ↓



Solution

Company A will need to evaluate its contract with the governmental entity, at the inception of the arrangement, to determine if it is probable that it will collect the amounts to which it is entitled in exchange for the prescription drugs. ASC 606 indicates that for purposes of determining the transaction price, the entity should consider the variable consideration guidance, including the possibility of price concessions. If, based on its historical experience, Company A expects to ultimately provide a price concession to collect its receivable, then the transaction price will be reduced by the amount of the expected price concession. Company A would then evaluate whether it is probable it will collect the adjusted transaction price. Assuming the collectibility hurdle is met, the transaction price will be recognized as Company A satisfies its performance obligation of delivering the drugs. Additionally, if by agreement or based on past experience with the governmental entity, the amount of time expected until collection exceeds one year, before concluding on the final amount of the transaction price, Company A will need to consider if there is a significant financing element in the arrangement based on the anticipated length of time between the sale of the prescription drug and expected payment from the governmental entity.

Finally, Company A will need to continually evaluate its outstanding receivables for impairment losses relating to the customer's credit risk. Company A needs to consider whether any subsequent billing adjustments are concessions granted to the customer (i.e., a modification to the transaction price) or a credit adjustment (i.e., a write-off of an uncollectible amount from the governmental entity). A modification of the transaction price reduces the amount of revenue recognized, while a credit adjustment is an impairment assessed under ASC 310, *Receivables*, and recognized as a bad debt expense. The facts and circumstances specific to the adjustment should be considered, including the entity's past business practices and ongoing relationship with a customer, to make this determination.

Refer to ASC 606 Example 1 – *Collectibility of the consideration* for additional guidance on this topic.

60. *Scope considerations when accounting for collaboration agreements*

Background



A biotech entity (“Biotech”) enters into an arrangement with a pharmaceutical entity (“Pharma”). Biotech grants an IP license to a drug compound to Pharma and will perform manufacturing services on the compound. Biotech receives an upfront payment of \$40 million, per-unit payments for manufacturing services performed, and a milestone payment of \$150 million upon regulatory approval. Consideration payable under this arrangement are at market rates and all payments received by Biotech are non-refundable.

Relevant guidance



ASC 606-10-15-3 states “An entity shall apply the guidance in this Topic to a contract...only if the counterparty to the contract is a customer. A customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity’s ordinary activities in exchange for consideration. A counterparty to the contract would not be a customer if, for example, the counterparty has contracted with the entity to participate in an activity or process in which the parties to the contract share in the risks and benefits that result from the activity or process (such as developing an asset in a collaboration arrangement) rather than to obtain the output of the entity’s ordinary activities.

Is this arrangement within the scope of ASC 606? ↓



Solution

Determining whether an arrangement is within the scope of ASC 606 can be a difficult judgment at times; however, in this case, the arrangement appears to be in the scope of the new revenue standard as Biotech and Pharma appear to have a vendor-customer relationship. Biotech is providing a license and manufacturing services to Pharma and those goods and services are the outputs of Biotech’s ordinary activities. The fees paid are at market rates and payments received are non-refundable. Also, the two companies do not appear to share in the risks and benefits that result from the activities under the arrangement.

61. Government vaccine stockpiles (solution updated as of April 5, 2017)

Background



Pharmaceutical companies sometimes sell vaccines to the United States government for placement into stockpiles. The Centers for Disease Control and Prevention (CDC) was charged with managing these stockpiles by the United States government for use in outbreaks of vaccine-preventable diseases as well as vaccine supply disruptions. Therefore, provisions for storage, rotation and orders against the stockpile are governed by individual contracts between a pharmaceutical manufacturer and the CDC.

Pharmaceutical companies will often retain the physical inventory that was sold into the stockpile at their own sites. Therefore, based on the specific terms, these contracts sometimes do not satisfy the following requirements under bill-and-hold guidance:

- The product must be identified separately as belonging to the customer.
- The entity cannot have the ability to use the product or to direct it to another customer.

How should companies account for these arrangements? ↓



Solution

To address the satisfaction of bill-and-hold requirements under ASC 605 relative to these arrangements with the CDC, the SEC issued the following interpretation: *the Commission will not object if vaccine manufacturers recognize revenue from the sale of enumerated vaccines related to Federal governmental stockpile programs if the arrangements meet the applicable revenue recognition criteria specified under generally accepted accounting principles and Commission rules and regulations, other than for the requirements associated with product delivery and inventory segregation [under bill-and-hold guidance], so long as disclosures are provided that allow for a clear understanding by investors of the subject transactions, the related accounting, and the effect of this alternative accounting method in the financial statements.*

We understand that the SEC will continue to review the applicability of the vaccine guidance under the new revenue recognition standard with a view toward providing clarity in the near future. As of the date of this publication, there has been no updated guidance from the SEC related to this matter. Stakeholders should remain alert for official releases or comments from the SEC on this topic.



Relevant guidance

A bill-and hold arrangement is a contract under which an entity bills a customer for a product but the entity retains physical possession of the product until it is transferred to the customer at a point in time in the future [ASC 606-10-55-81].

In addition to applying the guidance in paragraph 606-10-25-30, for a customer to have obtained control of a product in a bill-and-hold arrangement, all of the following criteria must be met:

- a. The reason for the bill-and-hold arrangement must be substantive (for example, the customer requested the arrangement).
- b. The product must be identified separately as belonging to the customer.
- c. The product currently must be ready for physical transfer to the customer.
- d. The entity cannot have the ability to use the product or to direct it to another customer [ASC 606-10-55-83].

62. Synthetic FOB destination

Background



Company A, a pharmaceutical drug manufacturer, sells pharmaceutical drugs to its customers. Company A's standard sales contracts contain "free on board" (FOB) shipping point terms, and it is clear that title legally transfers at the time the product is provided to the common carrier to be shipped to the customer. At the same time, Company A has a history of replacing or crediting lost or damaged shipments. When a customer indicates that a product has been lost or damaged, Company A provides the customer with a credit to their account or replaces the damaged product at no cost to the customer.

Upon shipment, Company A issues the invoice to the customer using customary payment terms. Over the last three years, customer claims averaged less than 0.2% of total orders and 0.1% of total revenues. Company A has reimbursed all claims for each of the last three years.

When should Company A recognize revenue from the sale of the products?



Solution

Under ASC 606, companies should carefully consider the indicators in ASC 606-10-25-30 as to when control transfers. There is judgment in determining when control transfers, and specific facts and circumstances to a transaction could impact this determination.

In this case, while there are mixed indicators as to when control transfers to the customer, it would appear that transfer of control occurs at the point of shipment. Company A would need to evaluate whether its past practice of replacing lost or damaged product represents a separate performance obligation or possibly a guarantee.

However, Company A may conclude that the promise to replace lost or damaged product is immaterial in the context of the contract and, as such, an assessment of this promise as a separate performance obligation is not required. Instead, the estimated costs to replace lost or damaged goods, developed using historical experience, would be accrued at the time revenue is recognized for the product shipment.

Irrespective of the determination as to whether or not the promise to replace lost or damaged product is a separate performance obligation, Company A may also consider electing the accounting policy to treat shipping and handling as activities to fulfill the promise to transfer the good.

Relevant guidance



The guidance in ASC 606-10-25-30 provides indicators of transfer of control, which include:


- The entity has a present right to payment for the asset.
- The customer has legal title to the asset.
- The entity has transferred physical possession of the asset.
- The customer has the significant risks and rewards of ownership of the asset.
- The customer has accepted the asset.

If shipping and handling activities are performed after a customer obtains control of the good, then the entity may elect to account for shipping and handling as activities to fulfill the promise to transfer the good [ASC 606-10-25-18B].


An entity is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer [ASC 606-10-25-16A].

63. Sales-based milestones

Background

 In the current year, Company A entered into an arrangement with Company B, whereby Company A has agreed to provide to Company B a license to its intellectual property. The license was transferred to Company B at contract inception. In return, Company B has paid Company A an up-front payment of \$10 million and may pay Company A an additional \$20 million in the event Company B's annual sales of products associated with this licensed intellectual property exceed \$250 million.

Relevant guidance

 ASC 606-10-32-5 states that if the consideration promised in a contract includes a variable amount, an entity shall estimate the amount of consideration to which the entity will be entitled in exchange for transferring the promised goods or services to a customer.

ASC 606-10-32-6: An amount of consideration can vary because of discounts, rebates, refunds, credits, price concessions, incentives, performance bonuses, penalties, or other similar items. The promised consideration also can vary if an entity's entitlement to the consideration is contingent on the occurrence or nonoccurrence of a future event. For example, an amount of consideration would be variable if either a product was sold with a right of return or a fixed amount is promised as a performance bonus on achievement of a specified milestone.

ASC 606-10-55-65 states, "Notwithstanding the guidance in paragraphs 606-10-32-11 through 32-14, an entity should recognize revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property only when (or as) the later of the following events occurs:

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

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

63. Sales-based milestones (continued)

How should Company A account for the contingent milestone consideration of \$20 million? ↓



Solution


We believe the \$20 million sales-based milestone should generally be viewed as a royalty given it is based solely on Company B's subsequent sales under or usage of the license to Company A's intellectual property. Because this example relates to the license of intellectual property and is a related sales-based royalty (milestone), the exception for sales-based or usage-based royalties applies.

Since the royalty exception applies to this scenario, instead of accounting for this milestone as variable consideration that is estimated and included in the transaction price at contract inception, the milestone is recognized at the later of (1) when the subsequent sales or usage occurs or (2) full or partial satisfaction of the performance obligation to which some or all of the sales-based royalty has been allocated.

Therefore, as Company A only had one performance obligation to deliver the license to Company B, which was delivered at the beginning of the contract, Company A should not recognize as revenue any portion of the \$20 million sales-based milestone until the subsequent sales mandating payment occur.

64. Receipts for out-licensing

Background

 Company A and Company B enter into an agreement in which Company A will license Company B's know-how and technology to manufacture a compound for HIV. Company B will not undertake any other activities under the contract. Company A will use Company B's technology for a period of three years. Company B obtains a non-refundable upfront payment of \$3 million for access to the technology. Company B will also receive a royalty of 20% from sales of the HIV compound if Company A successfully develops a marketable drug.

How should Company B account for a non-refundable upfront fee received for licensing out its know-how and technology to a third party? ↓




Solution

Given the intellectual property is a drug compound, it has standalone functionality and Company B does not perform any activities that affect that functionality. As such, Company B concludes that it has granted a "right to use" license to functional intellectual property. As a result, the non-refundable upfront payment of \$3 million is recognized at the point in time that the license is granted to Company A.

Company B applies the exception for variable consideration related to sales- or usage-based royalties received in exchange for licenses of intellectual property. Therefore, royalties are not included in the transaction price until Company A sells the product, regardless of whether or not Company B has predictive experience with similar arrangements.

Relevant guidance

 ASC 606-10-55-62 states "A license to functional intellectual property grants a right to use the entity's intellectual property as it exists at the point in time at which the license is granted unless both of the following criteria are met:

- a. The functionality of the intellectual property to which the customer has rights is expected to substantively change during the license period as a result of activities of the entity that do not transfer a promised good or service to the customer. Additional promised goods or services (for example, intellectual property upgrade rights or rights to use or access additional intellectual property) are not considered in assessing this criterion.
- b. The customer is contractually or practically required to use the updated intellectual property resulting from the activities in criterion (a)."

ASC 606-10-55-65 states "An entity should recognize revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property only when (or as) the later of the following events occurs:

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

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