

US GAAP

Issues and Solutions for the Pharmaceuticals and Life Sciences Industries



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Foreword

Accounting under US Generally Accepted Accounting Principles (US GAAP) continues to evolve and in today's world where there is a growing demand for greater transparency and heightened regulatory scrutiny; the need to ensure the proper accounting for transactions has never been greater. At the same time convergence with IFRS is becoming a reality rather than a possibility. Many non-US companies have already transitioned to IFRS and the SEC may provide US companies with an opportunity to make a similar switch.

Many publications have discussed the broader implications of US GAAP and IFRS but, to date, none has addressed the particular accounting issues the pharmaceutical and life sciences sector faces. The aim of this publication is to highlight the industry-specific factors which need to be considered, and to provide an opinion on the most pertinent accounting solutions for commercial situations under US GAAP. Separate publications have been produced by us addressing IFRS and together with this publication provide a comprehensive picture of certain industry related matters that companies are addressing.

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In reality, every company deals with accounting issues that should reflect the facts and circumstances of their particular situation. The solutions in this publication provide a framework for determining the appropriate accounting answer but individual fact patterns may give rise to a different answer. We cannot hope to address every situation that occurs – there is too much creativity in licensing arrangements to achieve that. Rather, the solutions cover several general situations. As new trends emerge, we will consider further editions of this publication.

We hope you find this publication useful in understanding the accounting for the transactions you encounter in your business. Further, we hope that by stimulating debate around these topics, we will encourage consistent practices by the pharmaceuticals and life sciences companies in financial reporting under US GAAP. This consistency will be critical to the continued acceptance and usefulness of pharmaceutical and life science entities' financial statements.

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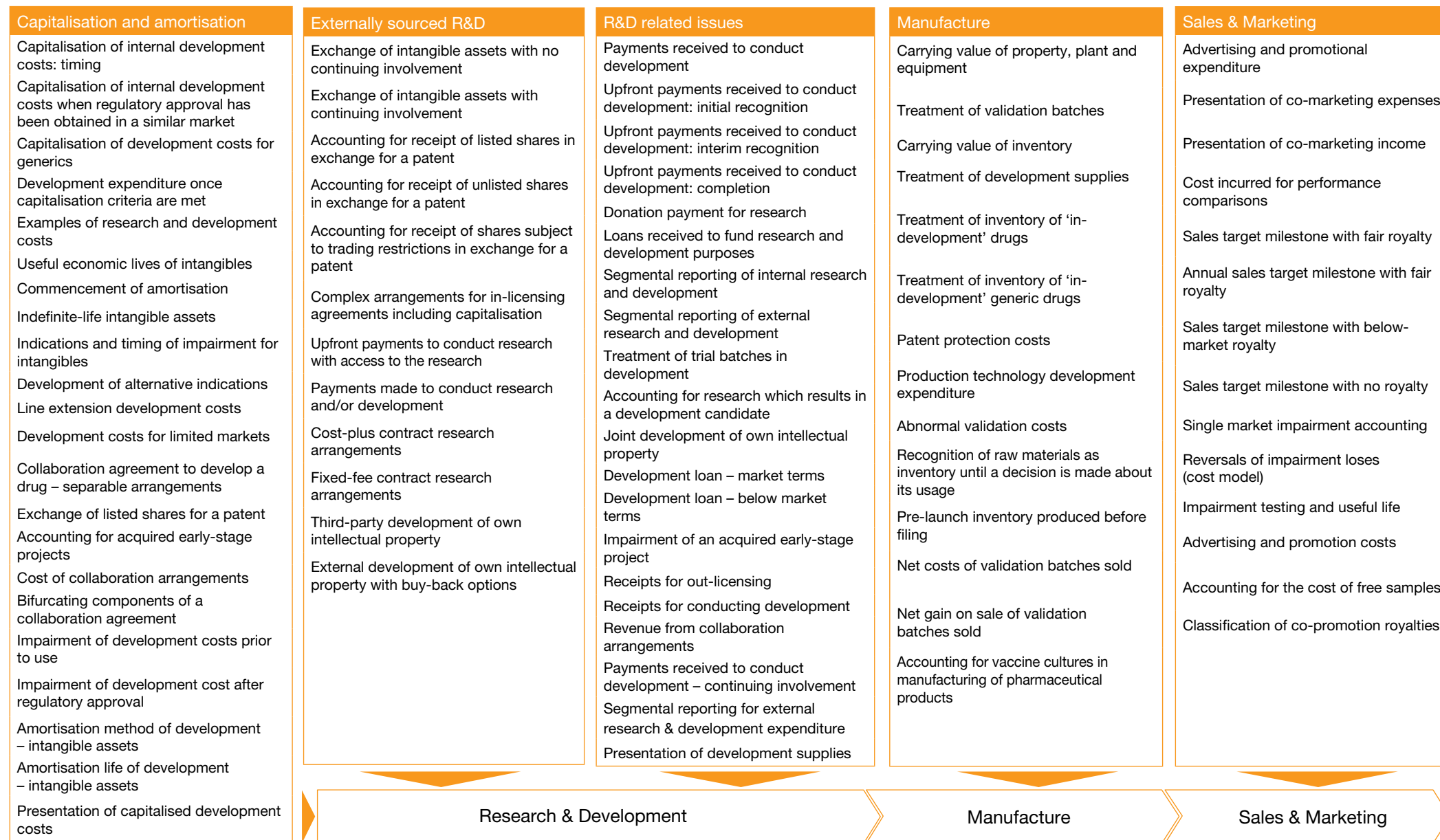


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The value chain and associated US GAAP accounting issues



1. Capitalisation of internal development costs: timing

Background

A company is developing a vaccine for HIV that has successfully completed Phases 1 and 2 of clinical testing. The drug is now in Phase 3 of clinical testing. Management still has significant concerns about securing regulatory approval and has not started manufacturing or marketing the vaccine.

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

How should management account for research and development costs incurred on this project? Would the answer change if the drug is similar to other drugs the entity has successfully developed in the past and management believes it will be favourably treated by the regulatory authority?

Solution

Costs to perform research and development (R&D), including internal development costs, should be expensed as incurred regardless of past history with similar drugs or regulatory authority approval expectations. There is no capitalisation of internal costs for R&D under US GAAP.

2. Capitalisation of internal development costs when regulatory approval has been obtained in a similar market

Background

Scenario 1: An entity has obtained scientific regulatory approval for a new respiratory drug in Country Agara. It is now progressing through the additional development procedures necessary to gain approval in Country Belan.

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

Scenario 2: An entity has obtained scientific regulatory approval for a new AIDS drug in Country Spartek and is progressing through the additional development procedures necessary to gain approval in Country Oceana.

Experience shows that significant additional clinical trials will be necessary to meet the Oceanese scientific regulatory approval requirements. Some drugs accepted in Spartek have not been accepted for sale in Oceana, even after additional clinical trials.

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

Should the development costs in each scenario be capitalised?

Solution

No, the company should expense development costs as incurred pursuant to FAS 2. Probability of success and past history do not impact the requirement to expense research and development costs as incurred.

3. Capitalisation 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 technical feasibility of the asset 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 should be expensed when incurred [FAS 2R.12].

Should management capitalise the development costs at this point?

Solution

No, research and development costs should be expensed when incurred.

4. Development expenditure once capitalisation criteria are met

Background

Scenario 1: MagicCure has obtained scientific regulatory approval for a new respiratory drug and is now incurring expenditure to educate its sales force and perform market research.

Scenario 2: DeltaB has determined that it has met the six criteria for capitalisation for a vaccine delivery device. It is now continuing expenditure on the device to add new functionality. The development of this device will require new scientific regulatory approval.

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

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 6R80].

Should the managements of MagicCure and DeltaB capitalise these costs?

Solution

MagicCure should expense sales and marketing expenditures such as training a sales force or performing market research as incurred.

DeltaB should not capitalise the expenditure it incurs to add new functionality as these costs would be considered research and development expenditures for the new indications and would be expensed as incurred. Note that the six criteria for capitalisation referred to in the Background is not applicable for US GAAP.

5. Examples of research and development costs

Background

A laboratory is developing a drug to cure SARS. But management is unsure what costs to include as R&D expenditures.

Relevant guidance

Research and development costs are defined in FAS 2R.8 and examples of such costs are presented in FAS 2R9 and R10.

What kinds of expenditure can be considered research and development costs in the pharmaceutical industry?

Solution

The following are examples of activities that typically would be considered research and development expenditures:

- 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 testing of pre-production prototypes and models.
- Design of tools, jigs, molds, and dies involving new technology.
- Design, construction, and operation of a pilot plant that is not of a scale economically feasible to the enterprise 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 [FAS 2R.9].
- Expenditures in the above activities could include materials, equipment or facility charges, compensation and benefits for personnel, intangible assets purchased from others (to the extent that they do not have alternative use or technological feasibility), the cost of contract services performed by others, and a reasonable allocation of indirect costs.

6. Useful economic lives of intangibles

Background

A laboratory has acquired a license to manufacture and sell a newly approved pharmaceutical drug.

What factors should management consider in its assessment of the useful life of the intangible asset (including ongoing reassessment of useful lives)?

Relevant guidance

The accounting for a recognised intangible asset is based on its useful life to the reporting entity.

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 [FAS 142R.11].

The remaining useful life of an intangible asset should be reviewed each reporting period to determine whether events and circumstances warrant a revision to the remaining period of amortisation [FAS 142R14].

Solution

Internal costs and external costs for R&D incurred prior to regulatory approval are generally expensed under US GAAP. External costs to acquire a license, product or right paid upon or after regulatory approval should be capitalised as intangibles pursuant to FAS 142. The useful life of assets, particularly those valued using a cash flow model, often cover the period over which substantially all of the cash flows of the asset are expected to occur. Management must also consider a number of factors that are relevant to all industries and the guidance in FAS 142R.11 when determining the useful life of an intangible asset. In addition to these factors, it should consider industry-specific factors, such as the following:

- Duration of the patent right or licence of the product;
- Redundancy of a similar medication/device due to changes in market preferences;
- Impact of bad publicity on a brand name (for example, a significant fall in sales arising from side-effects of a product or a product recall);
- Unfavourable court decisions on claims from product users;
- Regulatory decisions over patent rights or licences;
- Development of new drugs treating the same disease;
- Changes in the environment that make the product ineffective (for example, a mutation in the virus that is causing a disease, which renders it stronger);
- Changes or anticipated changes in participation rates or reimbursement policies of insurance companies; and
- Changes in government reimbursement or policies (i.e. Medicare, Medicaid) for drugs and other medical products.

7. Commencement of amortisation

Background

A company acquired a compound for \$5 million on 1 January 20X3. The entity amortises its intangible assets on a straight-line basis over the estimated useful life of the asset. The entity receives regulatory and marketing approval on 1 March 20X4 and starts using the compound in its production process on 1 June 20X4.

Relevant guidance

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. The method of amortising an intangible asset should reflect the pattern in which economic benefits of the intangible are used up [FAS 142R.11&12].

When should it begin amortising its intangible assets?

Solution

Because the compound was acquired prior to regulatory approval, the payment would be expensed under US GAAP as research and development (assuming there is no alternative future use). Had the compound been acquired after regulatory approval, the entity should begin amortising the intangible asset on the date when it is available for its expected use. This would generally be the acquisition date.

8. Indefinite-life intangible assets

Background

Management of a pharmaceutical entity has acquired an intangible asset that it believes has an indefinite useful life and has decided not to amortise it.

Can management regard the asset as having an indefinite life, and how should management account for it?

Relevant guidance

If no legal, regulatory, contractual competitive economic or other factors limit the useful life of an intangible asset, the useful life of the asset shall be considered to be indefinite [FAS 142R.11]. If an intangible asset is determined to have an indefinite useful life, it shall not be amortised until its useful life is determined to be no longer indefinite [FAS 142R.16].

An entity shall evaluate the remaining useful life of an intangible asset that is not being amortised each reporting period to determine whether events and circumstances continue to support an indefinite useful life. An intangible asset that is not subject to amortisation shall be tested for impairment annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired [FAS 142R.16 & R.17].

Solution

Yes, management can regard an asset as having an indefinite life in accordance with FAS 142. However, even though the asset is not amortised, management is required to test it for impairment, by comparing its fair value with its carrying value both annually and more often if there is an indication the intangible asset may be impaired (i.e. a triggering event occurs) [FAS 142R.17].

Pharmaceutical intangible assets that might be regarded as having an indefinite life could include acquired brands (i.e. 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 pharmaceutical products have indefinite economic lives.

9. Indications and timing of impairment for intangibles

Background

An entity has capitalised the cost of acquiring a respiratory product in Phase 3 development that it is not amortising, as it is not available for use.

What indicators of impairment should management consider?

Relevant guidance

An intangible asset should be evaluated for impairment as part of its assigned asset group if events or changes in circumstances indicate that the asset might be impaired [FAS 144R.8 and R.10]. An impairment loss should only be recognised if the carrying amount of the asset group is not recoverable from estimated undiscounted future cash flows of the asset group. In such cases an impairment loss shall be recognised in an amount equal to the excess of the asset group's carrying value over its fair value [FAS 144R.7].

Solution

There would be no asset recorded under US GAAP for products acquired prior to regulatory approval; however, if the product had been acquired subsequent to regulatory approval, FAS 144R.8 provides several examples of events or changes in circumstance (not all-inclusive) that management should consider when assessing whether an intangible asset should be tested for impairment.

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 licences;
- Failure of the drug's efficacy after a mutation in the disease that it is supposed to treat;
- Advances in medicine and/or technology that affect the medical treatments;
- Lower than predicted sales;
- Impact of publicity over brand names;
- Change in the economic lives of similar assets (see Solution 123.6 for discussion of useful lives);
- Relationship with other intangible or tangible assets; and
- Changes or anticipated changes in participation rates or reimbursement policies of insurance companies, Medicare and governments for drugs and other medical products.

10. Exchange of intangible assets with no continuing involvement

Background

Egram is developing a hepatitis vaccine compound. Fiorel is developing a measles vaccine compound. Egram and Fiorel enter into an agreement to swap the two products. Egram and Fiorel will not have any continuing involvement in the products that they have exchanged. The fair value of Egram's compound has been assessed as 3 million. The carrying value of the compound given up is zero as Egram has expensed all research and development costs associated with this unapproved product.

How should Egram's management account for the swap of vaccine products?

Would the accounting be different if the compound received by Egram had received regulatory and marketing approval prior to the exchange date?

Relevant guidance

An intangible asset may be acquired in exchange for a non-monetary asset or assets. The cost of the acquired intangible asset is measured at fair value unless:

- (a) the exchange transaction has no commercial substance,
- (b) the fair value of neither the asset received nor given up is reliably measurable or
- (c) the transaction is an exchange of a product held for sale in the ordinary course of business for a product to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange. [APB 29R.20 as amended by FAS 153].

The cost of the asset received should be based on the fair value of the asset surrendered unless the fair value of the asset received is more clearly evident [APB 29R.18].

A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. [FAS 153R.1].

Solution

In the situations noted, it is assumed that the exchange(s) has commercial substance; therefore, Egram's management should recognise the compound received at the fair value of the compound given up, which is LC 3 million. The transaction is assumed to have commercial substance in accordance with FAS 153, since future cash flows of both entities will change significantly once the vaccines are approved. Management should also recognise a gain on the exchange of LC 3 million. This gain does not take into account, or rather is not adjusted, for any difference between the fair market value of the asset given up and what the other company felt the FMV of their asset was, again, they are assumed to be equal.

Egram should immediately expense the value ascribed to the received compound as a research and development cost since the compound is not approved. If the compound was approved, Egram would capitalise LC 3 million to this asset and amortise over its useful life.

11. Exchange of intangible assets with continuing involvement

Background

Entity Giant is developing a hepatitis vaccine compound. Entity Hercules is developing a measles vaccine compound. Giant and Hercules enter into an agreement to swap these two products. Under the terms of the agreement, Giant will retain the marketing rights to its drug for all Asian countries. The fair value of Giant's compound has been assessed as \$3 million, including \$0.2 million relating to the Asian marketing rights. The carrying amount of the compound is \$0.5 million.

How should Giant's management account for the swap of vaccine products (comprising intellectual property), assuming that the transaction has commercial substance?

Relevant guidance

An intangible asset may be acquired in exchange for a non-monetary asset or assets. The cost of the acquired intangible asset is measured at fair value unless:

- (a) the exchange transaction has no commercial substance,
- (b) the fair value of neither the asset received nor given up is reliably measurable or
- (c) the transaction is an exchange of a product held for sale in the ordinary course of business for a product to be sold in the same line of business to facilitate sales to customers other than the parties to the exchange. [APB 29R.20 as amended by FAS 153].

The cost of the asset received should be based on the fair value of the asset surrendered unless the fair value of the asset received is more clearly evident [APB 29R.18].

A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. [FAS 153R.1].

Solution

In the situations noted, it is assumed that the exchange(s) has commercial substance; therefore, Giant's management should recognise the compound received at the fair value of the compound given up, which is \$2.8 million (\$3.0 million - \$0.2 million). The fair value of \$0.2 million relating to the marketing rights is excluded from the calculation because the rights have not been sold. Management should also recognise a gain on the exchange of \$2.8 million (consideration received of \$2.8 million less assumed carrying value of zero). Giant should immediately expense the value ascribed to the received compound as a research and development costs since the compound is not approved. If the compound was approved, Giant would capitalise LC 2.8 million to this asset and amortise over its useful life.

This scenario assumes Giant has no continuing involvement in the development of the hepatitis vaccine compound subsequent to the exchange which may be rare in practice due to involvement in steering committees, future development efforts, buy-back rights, etc. If Giant had continuing involvement in the hepatitis vaccine, it would need to consider whether the gain would need to be deferred and recognised over the continuing involvement period.

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

Background

Jerome agrees to acquire a patent from pharmaceutical group Kupla in order to develop a more complex drug. Jerome will pay for the right it acquires by giving Kupla 5% of its shares (which are listed). The listed shares represent the fair value of the patent. If Jerome is successful in developing a drug and bringing it to the market, Kupla will also receive a 5% commission on all sales. Kupla's management expects to classify the shares as available for sale.

Relevant guidance

An investor should record its investment in the stock of an investee at its cost [APB 18R.6a]. Equity securities that have readily determinable fair values shall be classified as trading securities or available for sale securities [FAS 115R.12].

The cost of the asset received should be based on the fair value of the asset surrendered unless the fair value of the asset received is more clearly evident [APB 29R.18].

How should Kupla's management account for the shares it receives?

Solution

Kupla's management should initially recognise the shares received as available-for-sale securities at their fair value. Kupla's management should also derecognise the patent that is transferred to Jerome, and should recognise the gain arising from the sale of the patent. The fair value of the shares received represents the amount of the consideration received and would be used to measure this transaction as it is more readily determinable (market quoted value) than is the value of the patent given up. Transaction costs would be recorded as a reduction of the gain on the sale of the patent.

Kupla should not yet recognise any asset relating to the future royalty stream from the potential sales of the drug, because this stream of royalties is contingent upon the successful development of the drug. The revenue will be recognised on an accrual basis, as the royalties are earned.

Following the rules for available-for-sale securities, Kupla should subsequently measure the shares at fair value at each balance sheet date. Movements in fair value should be recognised in equity, except for other than temporary impairment losses, which are charged to the income statement. Any subsequent recovery in the value of the security after the impairment loss would not reverse the impairment loss but would rather be recorded in equity. Management should also provide relevant disclosures relating to the key characteristics of the shares (i.e. restrictions).

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

Background

A company Rossel agrees to acquire a patent from pharmaceutical group Kupla in order to try to develop a more complex drug. Rossel will pay for the right it acquires by giving Kupla 10% of the shares in an unlisted subsidiary. If Rossel is successful in developing the drug and bringing it to the market, Kupla will receive a 5% commission on all sales. Management expects to classify these shares as available-for-sale.

Relevant guidance

An investor should record its investment in the stock of an investee at its cost [APB 18R.6a]. Equity securities that have readily determinable fair values shall be classified as trading securities or available for sale securities [FAS 115R.12].

The cost of the asset received should be based on the fair value of the asset surrendered unless the fair value of the asset received is more clearly evident [APB 29R.18].

How should Kupla's management initially recognise the shares it receives from Rossel in a collaboration agreement?

Solution

Generally, the fair value of the patent given up (i.e. an asset) will be more readily determinable than the fair value of the shares because these shares are of an unlisted subsidiary. FAS 115 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 (SEC) or in the over-the-counter market, or similar foreign market.

Consequently, Kupla's management would generally conclude that the fair value of the shares is the same value as the patent given up. Kupla's management should also derecognise the patent that is transferred to Rossel and should recognise the gain arising from the sale of the patent (fair value less carrying value of the patent). Transaction costs would be recorded as a reduction of the gain on the sale of the patent.

Kupla should not yet recognise any asset relating to the future royalty stream from the potential sales of the drug, because this stream of royalties is contingent upon the successful development of the drug. The revenue will be recognised on an accrual basis, as the royalties are earned.

14. Accounting for receipt of shares subject to trading restrictions in exchange for a patent

Background

Landra acquires a patent from pharmaceutical group Mixan in order to develop a more complex drug. Landra pays for the right it acquires by giving Mixan 15% of its listed shares. This does not give Mixan significant influence over Landra. The shares received by Mixan will have the following restriction: during the first two years, Mixan can only sell the shares to a third party at a price fixed in the agreement with Landra. Mixan's management expects to classify these shares as available-for-sale.

How should Mixan's management account for the shares it receives?

Relevant guidance

An investor should record its investment in the stock of an investee at its cost [APB 18R.6a]. Equity securities that have readily determinable fair values shall be classified as trading securities or available for sale securities [FAS 115R.12]. The price in the principal market used to measure the fair value of the asset or liability shall not be adjusted for transaction costs [FAS 157R.9] (Note that FAS 157 is effective for fiscal years beginning after November 15, 2007).

For individual securities classified as either available-for-sale, an enterprise shall determine whether a decline in fair value below the amortised cost basis is other than temporary. If the decline in fair value is judged to be other than temporary, the cost basis of the individual security shall be written down to fair value as a new cost basis and the amount of the write-down shall be included in earnings (that is, accounted for as a realised loss). The new cost basis shall not be changed for subsequent recoveries in fair value. Subsequent increases in the fair value of available-for-sale securities shall be included in other comprehensive income; subsequent decreases in fair value, if not an other-than-temporary impairment, also shall be included in other comprehensive income. [FAS 115R.16]

The cost of the asset received should be based on the fair value of the asset surrendered unless the fair value of the asset received is more clearly evident [APB 29R.18]. Fair value measurements should consider attributes specific to the asset and restrictions, if any, on the sale or use of the asset at the measurement date [FAS 157R.6].

Solution

Mixan's management should initially measure the listed shares received as available-for-sale securities at their quoted market price given that their value is readily determinable. The quoted market price should be adjusted for restrictions if a marketplace participant would consider those restrictions in determining the fair value of the securities. Note that FAS 157 is effective for years beginning after November 15, 2007. Prior to that date, restrictions are generally not considered in the determination of fair value of acquired shares.

Following the rules for available-for-sale securities, Mixan should subsequently measure the shares at fair value at each balance sheet date. Movements in fair value should be recognised in equity, except for other than temporary impairment losses, which are charged to the income statement. Any subsequent recovery in the value of the security after the impairment loss would not reverse the impairment loss but would rather be recorded in equity. Management should also provide relevant disclosures relating to the key characteristics of the shares (i.e. restrictions). Mixan should derecognise the intangible asset represented by the patent transferred to Landra and recognise any resulting gain or loss in the income statement.

15. Complex arrangements for in-licensing agreements including capitalisation

Background

Entities Regal and Simba enter into an agreement in which Regal will licence Simba's know-how and technology (which has a fair value of 3 million) to manufacture a compound for AIDS. It cannot use the know-how and technology for any other project. Regal's management has not yet concluded that economic benefits are likely to flow from this compound or that relevant regulatory approval will be achieved. Regal will use Simba's technology in its facilities for a period of three years. Simba will have to keep the technology updated and in accordance with Regal's requirements. The agreement stipulates that Regal make a non-refundable payment of 3 million to Simba for access to the technology. Simba will also receive a 20% royalty from sales of the protein compound.

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

If an asset acquired to be used in a current R&D activity has no alternative future use, the portion of the purchase price allocated to that asset be immediately charged to income by the combined enterprise [AICPA Practice Aid: Assets Acquired in a Business Combination Used in R&D – R3.1.01]

How should Regal's management account for the in-licensing agreement?

Solution

Regal's management should expense the LC 3 million when incurred as R&D expense since the know-how has no other alternative future use. When the drug is sold, Regal pays Simba 20% of sales. These payments are presented in the income statement, by nature (as part of operating expenses) or by function (generally as cost of sales). The method of presentation of expenses in the income statement should be applied consistently.

16. Upfront payments to conduct research with access to the research

Background

Astro engages a contract research organisation (CRO) to perform research activities for a period of two years in order to obtain know-how and try to discover a cure for AIDS. 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 Astro with the results of its research. Astro has full rights of access to all the research performed, including control of the research undertaken on the potential cure for AIDS. The CRO has no rights to use the results of the research for its own purposes.

Relevant guidance

All research and development costs encompassed by this Statement shall be charged to expense when incurred [FAS 2R.12].

Non-refundable advance payments for future research and development activities should be capitalised until the goods have been delivered or the related services have been performed. [EITF 07-03].

How should Astro account for upfront payments made to third parties to conduct research?

Solution

Although the payment is non-refundable, Astro will receive a future benefit as the CRO performs the research and should capitalise the upfront payment and amortise it as R&D expense as the CRO performs the research activities. Astro should continue to evaluate whether they expect the goods to be delivered or services to be rendered each reporting period to assess recoverability of the asset.

17. Payments made to conduct research and/or development

Background

Alpha, a small pharmaceutical company, contracts with the much larger BetaX to develop a new medical treatment for migraines over a five-year period. Alpha is engaged only to provide research and development services and will periodically have to update BetaX with the results of its work. BetaX has exclusive rights over the development results. It will make 20 equal non-refundable quarterly payments of LC 250,000 (totalling LC 5 million), if Alpha can demonstrate compliance with the development programme. Payments do not depend upon the achievement of a particular outcome. Alpha's management estimates the total cost will be LC 4 million.

In the first quarter of year one, Alpha incurs costs of 400,000, in line with its original estimate. Alpha is in compliance with the research agreement, including the provision of updates from the results of its work.

Relevant guidance

All research and development costs encompassed by this Statement shall be charged to expense when incurred [FAS 2R.12].

How should BetaX recognise the payments it makes Alpha?

Solution

BetaX should recognise research and development expense of LC 250,000 each quarter for as long as it authorises Alpha to continue performing the research. The straight-line method should be used for recognising the expense unless another method is more reflective of the effort performed by BetaX (i.e. proportionate performance).

18. Payments received to conduct development

Background

Alpha, a small pharmaceutical company, contracts with the much larger BetaX to develop a new medical treatment for migraine over a five-year period. Alpha is engaged only to provide development services and will periodically have to update BetaX with the results of its work. BetaX has exclusive rights over the development results. It will make 20 equal non-refundable payments of 250,000 (totalling 5 million), if Alpha can demonstrate compliance with the development programme. Payments do not depend upon the achievement of a particular outcome. Alpha's management estimates the total cost will be 4 million.

In the first quarter of year one, Alpha incurs costs of 400,000, in line with its original estimate. Alpha is in compliance with the research agreement, including the provision of updates from the results of its work.

Relevant guidance

Service revenues should be recognised on a straight-line basis, unless evidence suggests that the revenue is earned or obligations are fulfilled in a different pattern, over the contractual term of the arrangement or the expected period, during which those specified services will be performed, whichever is longer [SAB 104, Topic 13R.3f.Q2].

How should Alpha recognise the payments it receives from BetaX to conduct development?

Solution

If costs incurred are a reasonable representation of an output measure then Alpha should recognise the revenue on a proportional performance basis; otherwise, Alpha should recognise the revenue on a straight-line basis over the five-year period. This scenario assumes the development services are the only deliverable in the arrangement. If other deliverables existed, revenue should be allocated to each deliverable applying the guidance in EITF 00-21.

19. Upfront payments received to conduct development: initial recognition

Background

CareB has appointed Devox to develop an existing compound on its behalf. Devox will have no further involvement in the compound after regulatory approval. CareB will retain full ownership of the compound (including intellectual rights), even after scientific regulatory approval is obtained. Devox will not participate in any further marketing or production arrangements. A milestone plan is included in the contract. CareB agrees to make the following non-refundable payments to Devox:

- 3 million on signing of the agreement;
- 1 million on filing for stage 3 clinical trial approval; and
- 2 million on securing scientific regulatory approval.
- In addition, CareB will reimburse Devox for any expenditure incurred above 3 million prior to filing for stage 3 clinical trial approval.

Devox expects to incur costs totalling 3 million up to the point of filing for stage 3 clinical trial approval. But management cannot reliably estimate whether the compound will obtain stage 3 clinical trial approval or scientific regulatory approval.

Relevant guidance

Many arrangements require the customer to pay a certain amount of money at the start of the contract. These up-front payments are often characterised as non-refundable and are sometimes earmarked for “past services,” for “access” to some intangible right or for some general “rights.” Unless the up-front payment is in exchange for a product, service or right and represents the culmination of a separate earnings process, the up-front fee should be deferred over the longer of the contractual life of an arrangement or the customer relationship life. The customer’s perception of value received is paramount in this assessment. [SAB Topic 13].

How should Devox recognise the initial payment it has received from CareB?

Solution

Devox should record the initial payment as deferred income and recognise as income based on performance or on a straight line basis over the expected development period if development is performed evenly. At no point, however, should the revenue recorded exceed the amount of cash received. When the payment is initially received, no earnings process has been completed. No consideration should be given to the future milestone payments, as their receipt cannot be reliably estimated and no earnings process has been completed.

20. Upfront payments received to conduct development: interim recognition

Background

Devox is now in the process of fulfilling the contract with CareB outlined in the previous scenario. It has incurred 2 million in development costs from the inception of the contract on 1 March 20X1 through to 31 December 20X1, as projected in the original development plan.

How should it recognise deferred income and costs incurred to conduct development for another party?

Relevant guidance

Up-front fees, even if non-refundable, are earned as the products and/or services are delivered and/or performed over the term of the arrangement or the expected period of performance and generally should be deferred and recognised systematically over the periods that the fees are earned. A systematic method would be on a straight-line basis, unless evidence suggests that revenue is earned or obligations are fulfilled in a different pattern, in which case that pattern should be followed. Service revenue should be recognised on a straight-line basis, unless evidence suggests that the revenue is earned or obligations are fulfilled in a different pattern, over the contractual term of the arrangement or the expected period during which those specified services will be performed. [SAB Topic 13].

Solution

Devox should now recognise the deferred income it initially recorded. Devox should recognise the revenue on a straight-line basis or proportionally over the contract term based on the level of effort spent each period. Costs incurred may be an appropriate basis for measuring level of effort if the costs incurred are related to output measures such as man-hours or personnel costs. Initial set-up costs for materials, equipment or similar items should not be considered as they are generally not related to revenue generating activities. No consideration should be given to the future milestone payments, as their receipt cannot be reliably estimated and no earnings process has been completed.

It is important to note that CareB has no continuing involvement after the development phase in this scenario. If there was continuing involvement (i.e. co-marketing, manufacturing, steering committees), the terms of those contracts would need to be considered in determining the appropriate period to recognise the upfront payment as revenue.

21. Upfront payments received to conduct development: completion

Background

The compound on which Devox is working has now been filed for stage 3 clinical trial approval (Solution 123.19 and 123.20). CareB has paid the 1 million milestone payment specified in the development contract, in addition to the 3 million it paid on signing the contract. Devox has incurred costs of 3 million to reach this point, in line with original expectations, but management cannot reliably estimate whether it will be possible to obtain scientific regulatory approval for the compound.

How should deferred income, milestone receipts and costs incurred to conduct development for another party be recognised?

Relevant guidance

Up-front fees, even if non-refundable, are earned as the products and/or services are delivered and/or performed over the term of the arrangement or the expected period of performance and generally should be deferred and recognised systematically over the periods that the fees are earned. A systematic method would be on a straight-line basis, unless evidence suggests that revenue is earned or obligations are fulfilled in a different pattern, in which case that pattern should be followed. Service revenue should be recognised on a straight-line basis, unless evidence suggests that the revenue is earned or obligations are fulfilled in a different pattern, over the contractual term of the arrangement or the expected period during which those specified services will be performed. [SAB Topic 13].

Solution

Devox should continue to recognise the upfront payment based on either the straight-line or proportionate performance method it selected in the previous scenario. Several acceptable models exist for recognising milestone payments including the following:

- (1) Milestone method – Devox would recognise the milestone payment of LC 1,000,000 fully as revenue upon filing for stage 3 clinical trial approval. Generally to qualify for this method, the milestone events should have substance and represent the achievement of defined goals worthy of the payments. The following criteria could be used as guidance in making this judgemental assessment:
 - Substantive effort is involved in achieving each milestone
 - Milestone payments are reasonable in relation to the effort expended to achieve that milestone as well as the amount and level of effort relating to other milestone payments.
 - A reasonable amount of time should pass between the up-front payment and the first milestone, as well as between successive milestones
 - Consideration of the risk associated with each milestone
- (2) Proportional performance model (analogy to EITF 91-6) - Revenue is recognised in an amount equal to the lesser of (a) the amount due under the contract, or (b) amount based on proportional performance to date.
- (3) Contingency-adjusted performance model – Revenue is recognised based on the proportional performance to date at the time the milestone is achieved.
- (4) Contract deferral model – The milestone payment is deferred and recognised over the remaining term of the contract. Care should be used when selecting this method as it significantly back-ends recognition of revenue under the arrangement.

If the proportionate performance method was used for recognising the upfront payment, that method would generally be selected for accounting for the milestone payment as well. This would be a policy election which should be consistently applied by Devox.

If there were other deliverables included in the arrangement, Devox would need to allocate the revenue to each deliverable based on the guidance within EITF 00-21.

22. Donation payment for research

Background

Sherriff has made a non-refundable gift of LC 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. Sherriff has no right to access the research findings.

Relevant guidance

Contributions made shall be recognised as expenses in the period made and as decreases of assets or increases of liabilities depending on the form of the benefits given. Unconditional promises to give cash are recognised as payables and contribution expenses [FAS 116R.18].

Sherriff proposes to recognise the donation as an intangible asset.

Solution

Management should not recognise the donation as an intangible asset, irrespective of whether or not the company has access to the research findings. The donation should be expensed when made or at the time an unconditional promise to give is made, whichever is sooner, in the appropriate line item in the income statement (generally selling, general and administrative). If the donation will be made over time, Sheriff should discount the obligation to its present value in accordance with APB 21.

23. Loans received to fund research and development purposes

Background

Pilax has obtained a loan from Qula, another pharmaceutical company, to finance the late-stage development of a drug to treat cancer. Qula will have co-marketing rights over any product that is developed. Pilax's management has decided to capitalise all the development costs incurred after filing for scientific regulatory approval. Pilax applies the allowed alternative accounting treatment under IAS23 and capitalises borrowing costs on qualifying assets.

Relevant guidance

Interest shall be capitalised for the following types of assets ("qualifying assets") [FAS 34R9]:

- Assets that are constructed or otherwise produced for an enterprises own use
- Assets intended for sale or lease that are constructed or otherwise produced as discrete projects

Investments accounted for by the equity method while the investee has activities in progress necessary to commence its planned principal activities.

Can Pilax capitalise the interest incurred for borrowings obtained to finance R&D activities?

Solution

Borrowing costs associated with costs for research and development projects are expensed as incurred as development costs and do not qualify as assets under US GAAP (FAS 34).

24. Segmental reporting of internal research and development

Background

Alpha produces and sells a certain therapeutic group of drugs which is reported as a separate business segment in its financial statements. It funds the majority of its R&D activities internally in order to develop new drugs. It does not provide any significant R&D to external parties.

Should R&D activities be reported as a segment?

Relevant guidance

An operating segment is a component of an enterprise that:

- (a) engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same enterprise),
- (b) whose operating results are regularly reviewed by the enterprises chief operating decision maker(s), and
- (c) for which discrete financial information is available [FAS 131R. 10].

Solution

This determination depends on the manner in which Alpha's chief operating decision maker ("CODM") evaluates the business. If the R&D function recognises revenue for the services it provides to other components of the enterprise, the CODM regularly evaluates the revenues and operating results of the R&D function, and discrete financial information is available, the R&D function could be considered an operating segment. If this criteria is not met, costs of R&D activities should be assigned to Alpha's other operating segments based on the manner in which the CODM evaluates the segments. In other words, if R&D costs are allocated to the segments for purposes of the CODM evaluating the performance of the segment, then such costs would be included in the segment measure of profit and loss. If the profit measure the CODM uses to evaluate the segments does not include R&D costs, then such costs would be included as a reconciling item, similar to unallocated corporate costs.

25. Segmental reporting of external research and development

Background

Laboratory B has R&D facilities, which it uses to perform contract investigation activities for other laboratories and pharmaceutical companies. 60% of the laboratory's revenues are earned from external customers - and these external revenues represent 15% of the organisation's total revenues.

Should it report its R&D activities as a business segment?

Relevant guidance

An operating segment is a component of an enterprise that (a) engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same enterprise), (b) whose operating results are regularly reviewed by the enterprises chief operating decision maker(s), and (c) for which discrete financial information is available [FAS 131R. 10].

An enterprise shall report separately information about an operating segment that meets any of the following quantitative thresholds:

- (a) its reported revenue, including both sales to external customers and intersegment sales or transfers, is 10% or more of the combined revenue, internal and external, of all operating segments;
- (b) the absolute amount of its reported profit or loss is 10% or more of the greater, in absolute amount, of the combined reported profit of all operating segments that did not report a loss or the combined reported loss of all operating segments that did report a loss; or
- (c) its assets are 10% or more of the combined assets of all operating segments [FAS 131R. 18].

Solution

This determination depends on the manner in which Laboratory B's chief operating decision maker ("CODM") evaluates the business. If the R&D function recognises revenue for the services it provides to other components of the enterprise, the CODM regularly evaluates the revenues and operating results of the R&D function, and discrete financial information is available, the R&D function could be considered an operating segment. If this criteria is not met, the costs of R&D activities should be assigned to Alpha's other operating segments based on the manner in which the CODM evaluates the segments. In other words, if R&D costs are allocated to the segments for purposes of the CODM evaluating the performance of the segment, then such costs would be included in the segment measure of profit and loss. If the profit measure the CODM uses to evaluate the segments does not include R&D costs, then such costs would be included as a reconciling item, similar to unallocated corporate costs.

26. Treatment of trial batches in development

Background

A 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 3 clinical testing, and they cannot be used for any other purpose. The raw materials can be used in the production of other drugs.

Relevant guidance

The costs of materials, whether from the enterprise's normal inventory or acquired specially for research and development activities, that are acquired for research and development activities and have no alternative future uses (in research and development projects or otherwise) shall be expensed as incurred [FAS 2R. 11a].

How should management account for the raw materials and trial batches?

Solution

Management should initially capitalise the raw materials acquired in inventory as the materials have alternative future use in the production of an approved drug. As the trial batches do not have any alternative future use and the technical feasibility of the drug is not proven, the trial batches (including identified raw materials) should be charged to development expense when they are produced.

27. Carrying value of property, plant and equipment

Background

When assessing the carrying value of property, plant and equipment (PPE),

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 [FAS 144R.8].

What impairment indicators should a pharmaceutical (or life science) entity consider?

Solution

Management of all entities should consider the general indicators given in paragraph 8 of FAS 144, when assessing whether there is an impairment of PPE. In addition, pharmaceutical entities should also consider industry-specific factors such as the following (not meant to be all-inclusive):

- Patent expiry date;
- Failure of the machinery to meet regulatory requirements;
- Technical obsolescence of the PPE (for example, because it cannot accommodate new market preferences);
- Market entrance of competitive products;
- Product recall and/or changes in the environment that makes the underlying product ineffective;
- Unfavourable court decision;
- Side-effects and related bad publicity
- Relationship with other tangible and intangible assets; and
- Changes or anticipated changes in third-party reimbursement policies.

28. Treatment of validation batches

Background

A laboratory has just completed the development of a 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.

Relevant guidance

Property, plant, and equipment should be recorded at their historical cost which is the amount of cash, or its equivalent, paid to acquire an asset, which includes directly attributable expenditures incurred in acquiring the equipment and preparing it for use [CON 5 (para 67A)].

Should expenditure to validate machinery be capitalised?

Solution

The laboratory should capitalise the costs incurred (including materials, labour, 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 miscalculations during the validation process or revalidation costs (such as wasted material, labour or other resources).

29. Carrying value of inventory

Background

Cerise carries a significant amount of inventory.

Relevant guidance

When there is evidence that the value of goods, in their disposal in the ordinary course of business, will be less than cost, whether due to physical deterioration, obsolescence, changes in price levels, or other causes, the difference should be recognised as a loss of the current period [ARB 43 Ch.4 St. 5-6].

What factors should management consider in order to assess whether the inventory is worth less than cost (lower cost or market)?

Solution

There are a number of general indications that management should consider when inventory for recovery. Pharmaceutical entities should also consider industry-specific factors such as the following:

- Patent expiry date;
- Inventory expiry date;
- Market entrance of similar products (e.g. generics);
- Changes in medical treatments;
- Advances in medicine;
- Product recalls; and
- Changes or anticipated changes in third-party reimbursement policies.

30. Treatment 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 3 clinical tests. They can also be used for other testing purposes. Management is considering whether the batches should be recorded as an asset.

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

Relevant guidance

The costs of materials, whether from the enterprise's normal inventory or acquired specially for research and development activities, that are acquired for research and development activities and have no alternative future uses (in research and development projects or otherwise) shall be expensed as incurred [FAS 2R. 11a].

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 [FASB Concept Statement No. 6R. 26].

Solution

The batches do not meet the definition of inventory, but 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 R&D expense as consumed in development.

31. Treatment of inventory of 'in-development' drugs

Background

Laboratory A has produced 15,000 doses of a new drug, following submission of the final filing for regulatory approval, so that it can go to market with the drug as soon as it gets scientific regulatory approval. The doses cannot be used for any other purpose. Management is considering whether the doses should be recorded as inventory.

How should the costs associated with the production of inventory for 'in-development' drugs be accounted for?

Relevant guidance

The term inventory is used to designate the aggregate of those items of tangible personal property which:

- (1) are held for sale in the ordinary course of business,
- (2) are in process of production for such sale, or
- (3) are to be currently consumed in the production of goods or services to be available for sale [ARB 43 Ch. 4 St. 1].

Assets are probable future economic benefits obtained or controlled by a company as a result of past transactions or events [Con 6R.25]

Solution

Laboratory A should capitalise the doses it has produced to the extent that they are recoverable. If final filing for regulatory approval indicates that marketing approval is probable, these items of inventory can be treated as fully recoverable (assuming the inventory will be sold and usable prior to expiration). An assessment of likelihood that regulatory approval will not be obtained should be made at each reporting period. If at any time regulatory approval is deemed to not be probable, the inventory should be written down to its net realisable value which is presumably zero assuming that the product cannot be sold.

32. Treatment of inventory of 'in-development' generic drugs

Background

Tina Pharmaceuticals developed a generic version of an original drug whose patent is due to expire at the end of 20X3. Management believed the generic version was the chemical equivalent of the original drug and that economic benefits were probable.

Tina produced 15,000 doses of pre-launch inventory of the generic drug in June 20X3. The doses cannot be used for any other purposes. The patent on the original drug expired and marketing approval for the generic version was received in November 20X3. Management is considering whether the cost of the pre-launch inventory should be capitalised.

Relevant guidance

The term inventory is used to designate the aggregate of those items of tangible personal property which (1) are held for sale in the ordinary course of business, (2) are in process of production for such sale, or (3) are to be currently consumed in the production of goods or services to be available for sale [ARB 43 Ch. 4 St. 1].

Assets are probable future economic benefits obtained or controlled by a company as a result of past transactions or events [Con 6R.25]

How should the costs associated with the production of inventory for generic drugs 'in development' be accounted for?

Solution

Pre-launch inventory should be recorded as inventory at the lower of its cost or net realisable value. Management's conclusion that the generic drug is the chemical equivalent of the original drug, and that economic benefits are probable, support the conclusion that such inventory is commercially viable. Accordingly, the pre-launch inventory costs are realisable (assuming the inventory will be sold and used prior to expiration). Approval for marketing was received before the end of the year, showing that the inventory has not been impaired. An assessment of likelihood that regulatory approval will not be obtained should be made at each reporting period. If at any time regulatory approval is deemed to not be probable, the inventory should be written down to its net realisable value which is presumably zero assuming that the product cannot be sold.

33. Advertising and promotional expenditure

Background

A 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 TV commercials and presentations in conferences and seminars for doctors.

Relevant guidance

The costs of advertising should be expensed either as incurred or the first time the advertising takes place except for direct response advertising or expenditures for advertising that are made subsequent to recognising revenues related to such costs [SOP 93-7R. 26].

How should these costs be accounted for?

Solution

The company should not recognise its advertising and promotional costs as an intangible asset, even though the expenditure incurred may provide future economic benefits; it should charge all promotional costs to the income statement as incurred or the first time the advertising takes place based on the policy it has selected pursuant to SOP 93-7.

The presentation of promotional costs in the income statement will depend on the analysis of expenses preferred by management (by nature or by function). Promotional costs should be classified as advertising and promotional costs if the analysis of expenses is presented by nature; however, more detailed analysis may be provided. Promotional costs should be included within marketing expenses if the analysis of expenses is presented by function.

34. Presentation of co-marketing expenses

Background

Gena and Himen have entered into a co-marketing agreement for a compound XY, developed by Himen, for a period of ten years. The agreement is material for both parties. Under the terms of the agreement, Gena has made an upfront payment and milestone payments based on the achievement of certain goals, such as receipt of approval from the regulatory authorities. In return, Himen has granted Gena exclusive marketing rights for XY in Japan.

Himen will manufacture the product and sell it to Gena at cost. Gena will also pay Himen 20% of its net sales of XY and will share a portion of any potential product liability. The promotion and commercialisation of drugs are Gena's main activities, although in this case they are performed jointly with a third party.

Relevant guidance

A company should recognise revenue based on (a) the gross amount billed to a customer because it has earned revenue from the sale of the goods or services or (b) the net amount retained because it has earned a commission or fee depending on the relevant facts and circumstances [EITF 99-19R.6].

How should Gena present its co-marketing expenditure in its financial statements?

Solution

Gena's accounting for its co-marketing expenditures will vary depending on its conclusion on whether it is the principal or agent in the arrangement based on the factors discussed in EITF 99-19. If Gena determines it is the principal in the Japan market, Gena should present the payments received from customers as sales revenue, and the cost of purchasing XY from Himen as inventory and then cost of goods sold. The co-marketing amounts paid to Himen of 20% of net sales of the product represents a royalty in return for the product rights in that territory and should be presented as cost of goods sold.

If Gena were to determine it was the agent in the Japan market, it would recognise revenue calculated as payments due from customers less payments owed to Himen.

35. Presentation of co-marketing income

Background

Gena and Himen have entered into a co-marketing agreement for a compound XY, developed by Himen, for a period of ten years. The agreement is material for both parties. Under the terms of the agreement, Gena has made an upfront payment and milestone payments based on the achievement of certain goals, such as receipt of approval from the regulatory authorities. In return, Himen has granted Gena exclusive marketing rights for XY in Japan.

Himen will manufacture the product and sell it to Gena at cost. Gena will also pay Himen 20% of its net sales of XY and will share a portion of any potential product liability. The promotion and commercialisation of drugs are Gena's main activities, although in this case they are performed jointly with a third party.

Relevant guidance

A company should recognise revenue based on (a) the gross amount billed to a customer because it has earned revenue from the sale of the goods or services or (b) the net amount retained because it has earned a commission or fee depending on the relevant facts and circumstances [EITF 99-19R.6].

Revenue generally is realised or realisable and earned when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collectibility is reasonably assured [SAB 104R.A1].

How should Himen present the co-marketing income it receives from Gena in its financial statements?

Solution

Himen would first need to allocate the revenue under the arrangement to the various revenue elements using the guidance in EITF 00-21. Himen's accounting for its co-marketing income will then vary depending on its conclusion on whether it is the principal or agent in the arrangement based on the factors discussed in EITF 99-19. Assuming Himen determines that Gena is the principal for sales in Japan, Himen should recognise 100% of the sales of product XY to Gena as sales revenue and the corresponding costs of production as cost of sales. The co-marketing income, at 20% of Gena's sales, should be presented as royalty income and disclosed separately as a component of revenue, if material.

36. Development of alternative indications

Background

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

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

Should Arts capitalise any of the development costs?

Solution

Costs to perform research and development, including internal development costs, should be expensed as incurred regardless of past history with similar drugs or regulatory authority approval expectations.

37. Line extension development costs

Background

Degas Pharma owns a drug that has historically been approved for its pain-reducing effect on adults. Management now intends to obtain scientific approval to use the drug for the treatment of children. Degas has commenced additional development procedures necessary to gain approval for this line extension. Regulatory approval is needed for this line extension and the probability of obtaining approval is comparable to that of a new drug.

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

Should Degas capitalise any of the development costs?

Solution

Costs to perform research and development, including internal development costs, should be expensed as incurred regardless of past history with similar drugs or regulatory authority approval expectations.

38. Cost incurred for performance comparisons

Background

Van Gogh Ltd. has obtained regulatory approval for its new antidepressant drug and has started commercialisation. Van Gogh is now undertaking studies to verify the advantages of its drug over competing drugs already on the market. These studies will support Van Gogh's sales efforts.

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

How should Van Gogh treat the costs incurred?

Solution

The expenditure incurred for studies to identify performance features should be expensed as incurred. This expense should be included in the appropriate income statement classification based on the nature of the expenditure. The studies are directed at providing marketing support and the nature of the amounts spent is that of a marketing expense.

39. Development costs for limited markets

Background

Da Vinci Pharma is currently developing a drug that will be used in the treatment of a very specific ailment affecting a small group of patients. Da Vinci has filed for initial regulatory approval.

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

Should Da Vinci capitalise any of the development costs?

Solution

Costs to perform research and development, including internal development costs, should be expensed as incurred regardless of past history with similar drugs or economic or regulatory authority approval expectations.

40. Cost-plus contract research arrangements

Background

Whistler Corp. enters into a contract research arrangement with Ruskin Inc. to perform research on the geometry of a library of molecules. Ruskin will catalogue the research results in a database.

Whistler will refund all of Ruskin's direct costs incurred under the contract, plus paying a 25% premium on a quarterly basis as the work is completed.

Relevant guidance

An enterprise that incurs a liability to repay the other party(s) for research and development shall charge the research and development costs to expense as incurred [FAS 68R. 9]. The costs of services performed by others in connection with the research and development activities of an enterprise, including research and development conducted by others in behalf of the enterprise, shall be included in research and development costs [FAS 2R11.d].

How should pharmaceutical entities account for contracted research arrangements?

Solution

Whistler should expense costs for the contract research (including the premium) as the costs are incurred by Ruskin. The activity is within the definition of research.

41. Fixed-fee contract research arrangements

Background

Whistler Corp. enters into a contract research arrangement with Ruskin Inc. to perform research on the geometry of a library of molecules. Ruskin will catalogue the research results in a database.

Whistler will pay Ruskin LC3 million upon completion of the contracted work. The payment is based on delivery of the research services; there is no success-based contingency.

Relevant guidance

If the enterprise is obligated to repay any of the funds provided by the other parties regardless of the outcome of the research and development, the enterprise shall estimate and recognise that liability and record expense as incurred [FAS 68R. 5]. The costs of services performed by others in connection with the research and development activities of an enterprise, including research and development conducted by others in behalf of the enterprise, shall be included in research and development costs [FAS 2R11.d].

How should pharmaceutical entities account for contracted research arrangements?

Solution

Whistler should accrue the contract research costs over the expected period of the research. The costs are expensed as Rusin performs the service and recorded as research expense. The activity is within the definition of research. The structuring of the payments does not alter the accounting treatment.

42. Patent protection costs

Background

Velázquez Pharma has a registered patent on a currently marketed drug. Uccello Medicines Ltd. copies the drug's active ingredient and sells the drug during the patent protection period. Velázquez goes to trial and is likely to win the case, but has to pay costs for its attorneys and other legal charges.

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]. 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 [Con 6R.247].

If defence of a patent lawsuit is successful, costs may be capitalised to the extent of an evident increase in the value of the patent. Legal costs which relate to an unsuccessful outcome should be expensed [AICPA TIS 2260R.03].

Should legal costs relating to the defence of pharmaceutical patents be capitalised?

Solution

The accounting treatment (i.e. capitalise or expense as incurred) would depend upon Velázquez' policy for accounting for patent defence costs which should be consistently applied. Velázquez would not capitalise patent defence costs unless it believed it was probable the patent would be successfully defended and it could determine an evident increase in the value of the patent as a result of the defending the suit. In many cases, defence of a patent would maintain rather than increase the expected future economic benefits from the patent. Accordingly, patent defence costs would generally be expensed as incurred.

43. Accounting for research which results in a development candidate

Background

Sisley Pharma contracts with Wright Pharma to research possible candidates for further development in its anti-hypertension program. Sisley pays Wright on a cost-plus basis for the research, plus LC100,000 per development candidate which Sisley elects to pursue further. Sisley will own the rights to any such development candidates. After two years, Wright succeeds in confirming 10 candidates that will be used by Sisley.

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

How should payments for pharmaceutical research that subsequently becomes development be accounted for?

Solution

Costs to perform research and development should be expensed as incurred. Accordingly, Sisley's payments relating to the cost-plus portion should be expensed as incurred and the additional costs relating to the successful development candidates (LC 200,000) should be expensed when it is probable Sisley will elect to pursue further.

44. Third-party development of own intellectual property

Background

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

- LC2 million on signing the agreement
- LC3 million on successful completion of phase 2

Relevant guidance

Research and development costs should be expensed when incurred [FAS 2R.12].

Non-refundable advance payments for future research and development activities should be capitalised until the goods have been delivered or the related services have been performed. [EITF 07-03]

How should pharmaceutical entities account for upfront payments and subsequent milestone payments in a long-term research and development (R&D) arrangement in which a third party develops their intellectual property?

Solution

Tiepolo owns the compound and Tintoretto performs development on Tiepolo's behalf. The initial upfront payment represents a prepayment for funding development by a third party which should be expensed as Tintoretto performs the research. Tiepolo should expense the milestone payment when it is probable the payment will be made.

45. Joint development of own intellectual property

Background

Tiepolo Pharma has appointed Tintoretto Laboratories, a third party, to develop an existing compound owned by Tiepolo on its behalf. The agreement effectively out-licenses Tiepolo's compound to Tintoretto. Tiepolo and Tintoretto will set up a development steering committee to jointly perform the development and will participate in the funding of the development costs according to specific terms. Tiepolo agrees to make the following payments to Tintoretto:

- LC5 million on signing the agreement as an advance payment. Tintoretto has to refund the entire payment in the event of failure in development.
- 50% of total development costs on successful completion of phase 2 (after deducting the advance payment).
- In the case of successful completion of development and commercialisation, Tintoretto will receive milestone payments and royalty streams.

Relevant guidance

The costs of services performed by others in connection with the research and development activities of an enterprise, including research and development conducted by others in behalf of the enterprise, shall be included in research and development costs. [FAS 2R.11d].

To the extent that the financial risk associated with the research and development has been transferred because repayment of any of the funds provided by the other parties depends solely on the results of the research and development having future economic benefit, the enterprise shall account for its obligation as a contract to perform research and development for others [FAS 68R.10].

Non-refundable advance payments for future research and development activities should be capitalised until the goods have been delivered or the related services have been performed. [EITF 07-03]

How should pharmaceutical entities account for upfront payments and subsequent milestone payments in a long-term R&D arrangement in which a third party develops their intellectual property?

Solution

Tintoretto becomes party to substantial risks in the development of Tiepolo's compound, as it is only partly compensated for its development activities if the development succeeds (thereby buying into the potential success of the future product). Tiepolo effectively reduces its exposure to ongoing development costs and to potential failure of the development of its compound. The payments represent advance funding for future (in the case of the upfront payment) and past (for milestone payment) development of its own intellectual property by a third party. Therefore, the advance payment should be initially capitalised as a prepaid service asset and expensed over the development period commencing when successful development of the compound is probable. The milestone payment should be expensed over the Phase 2 development period commencing when successful completion of Phase 2 is probable.

Tiepolo should consider whether Tintoretto has the financial wherewithal to repay the advance payment if the development is unsuccessful. If Tintoretto does not have the ability to repay the advance if the drug is not successful or collectibility is otherwise uncertain, Tiepolo should amortise the advance payment and milestone over the development period.

46. External development of own intellectual property with buy-back options

Background

Tiepolo Pharma has appointed Tintoretto Laboratories, an independent, financially robust third party, to develop an existing compound owned by Tiepolo on its behalf. The agreement effectively out-licenses Tiepolo's compound to Tintoretto. Tiepolo 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 final submission of relevant documents for regulatory approval in the key markets, Tiepolo has the option to buy back the right of commercialisation of its compound. The following terms are agreed:

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

How should pharmaceutical entities account for upfront payments and subsequent milestone payments in a long-term R&D arrangement in which a third party develops their intellectual property?

Solution

Tintoretto takes all risks in the development of Tiepolo's compound, being compensated only for its development activities in the case of success (thereby buying itself into the potential success of the future product). Tiepolo effectively removes its exposure to failure of the development of its compound, having transferred all development risks to Tintoretto. By paying the agreed buy-back option, Tiepolo reacquires the commercialisation right intangible asset; however, since the payment is triggered upon filing for regulatory approval Tiepolo would be expense the payment as research and development. If Tiepolo were to make the payment when regulatory approval of the project is received, the buyback payments and future milestone payments would be capitalised when paid (or when probable in the case of the milestone payments) and then amortised over the useful life of the commercialisation right.

Tintoretto should consider whether the counterparty in similar arrangements would be variable interest entities for which it would need to consider whether it would be required to consolidate the entity under FIN 46.

Relevant guidance

If an enterprise is obligated to repay any of the funds provided by other parties regardless of the outcome of the research and development, the enterprise shall estimate and recognise that liability. To conclude that a liability does not exist, the transfer of the financial risk involved with the research and development from the enterprise must be substantive and genuine [FAS 68R.5 and R.6].

The following are examples of conditions leading to the presumption that an enterprise will repay the other parties [FAS 68R.8]:

- The enterprise has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development.
- The enterprise 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 enterprise and the parties funding the research and development at the time the enterprise enters into the arrangement.
- The enterprise has essentially completed the project before entering the arrangement.
- If the enterprises obligation is to perform research and development for others and the enterprise 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 [FAS 68R.11].
- The costs of services performed by others in connection with the research and development activities of an enterprise, including research and development conducted by others in behalf of the enterprise, shall be included in research and development costs [FAS 2.11d].

