Ihre Ansprechpartner

Sehr geehrte Damen und Herren,

für Rückfragen zu der beigefügten Publikation „In brief“ zur Thematik „Accounting for priority review vouchers (pharma industry)“ stehen Ihnen folgende Ansprechpartner gerne zur Verfügung:

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In brief
A look at current financial reporting issues

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Accounting for priority review vouchers (pharma industry)

Issue

To encourage the development of drugs that treat tropical and rare diseases, the Food and Drug Administration Amendments Act of 2007 granted the Food and Drug Administration ('FDA') the authority to award a Tropical Disease Priority Review Voucher ('TD-PRV') to a company that receives marketing approval for one of 16 neglected tropical diseases. Inspired by the TD-PRV program, the 2012 FDA Safety and Innovation Act provides companies with a Pediatric Priority Review Voucher ('Pediatric-PRV') for sponsoring a rare pediatric disease product application.

Both the TD-PRV and Pediatric-PRV ('Voucher') entitle the holder to ask the FDA for priority review of any future drug application that would otherwise get a standard review. The holder can use the Voucher on one of its own applications or sell it to another company. The Voucher does not guarantee that the FDA will approve the drug application.

This In brief addresses how to account for the purchase of a TD-PRV or a Pediatric-PRV from another company. Although sales have been limited, the price paid to acquire a Voucher has been significant, ranging from $65 million to $250 million.

Impact

Accounting considerations – IFRS

A priority review voucher meets the definition of an intangible asset under IAS 38, 'Intangible assets'. An intangible asset needs to be identifiable; controlled by the entity and gives rise to future economic benefits. An asset is identifiable if it is either separable or arises from a contractual or legal right.

The Voucher is identifiable as it can be sold or transferred to another company and arises from a legal right. The Voucher allows a company to fast track a review with the FDA, saving costs and potentially accelerating the time to market. A company can realise revenue faster if the review is successful or can move forward with another compound earlier if the review is unsuccessful. The owner of the Voucher therefore has the power to obtain future economic benefits.

The recognition criteria in paragraph 25 of IAS 38 are met when an intangible is separately acquired. The price paid reflects the expectation of future economic benefits and the cost can be reliably measured. A separately acquired Voucher can therefore be recognised on the balance sheet at cost. Nothing will be recognised on the balance sheet when the FDA issues the initial voucher for no cost.

A company will subsequently need to assess whether the useful life of the Voucher is finite or indefinite under paragraph 88 of IAS 38. The Voucher has a finite life which ends at the point the priority review has been committed and used with the FDA or the Voucher is sold to another company. The useful life of an intangible cannot be longer than any legal or contractual terms however the Voucher has no expiration date. The asset is consumed on a unit of production basis (when used) and therefore this is the most appropriate amortisation method. As such, the Voucher will be amortised in full when the Voucher is used and should be tested for impairment in the intervening period if there is a triggering event.

Accounting considerations – US GAAP

A company that acquires a Voucher can use it to accelerate the FDA review of its own drug application or sell the Voucher to another company. We believe the acquirer's intended use for the Voucher at the time of acquisition is key in determining the manner in which the Voucher is recognised and classified in its financial statements. Accounting Standards Codification (ASC) 730, *Research and Development*, provides guidance on how to account for intangible assets purchased from others for use in research and development (R&D) activities that were not part of a business combination.

Capitalise upon acquisition

If the acquirer is uncertain as to how the Voucher will be used, the cost paid to acquire the Voucher should be capitalised on the acquisition date. This is supported by ASC 730-20-25-13, which indicates that nonrefundable advance payments for goods that will be used for future R&D activities should be deferred and capitalised. Capitalising the payment made to purchase the Voucher also indicates that the Voucher has probable future economic benefit (by accelerating FDA review of a future drug application or through potential sale to another company), and therefore should be recorded as an asset to defer the acquisition cost until those benefits are realised.

At the time the acquirer commits to using the Voucher with the FDA to accelerate the review of a drug application, the cost paid to obtain the Voucher should be recorded as R&D costs. The 'commitment' occurs when the acquirer notifies the FDA of its intent to use the Voucher for its own product and the Voucher is no longer available to be sold to another party. Alternatively, if the Voucher is sold, the capitalised asset would be derecognised from the balance sheet. Any difference between the cost paid to obtain the Voucher and the proceeds received from its sale would be recognised in the income statement.

Expense upon acquisition

At the time the Voucher was acquired, if the company's intent was to fast track its own product application on an existing R&D project, we believe it

would be acceptable to immediately expense the cost paid to acquire the Voucher. This view is supported by the R&D guidance in ASC 730-10-25-2(c), which indicates that the cost of intangibles purchased from others for a particular R&D project that have no alternative future uses are R&D costs and are expensed at the time they are incurred. The key judgment underlying this position is that the Voucher will not be sold and does not have an alternative future use. Using the Voucher for another unapproved drug (that is, a second R&D project that has already commenced) would not meet the definition of an alternative future use since the second R&D project is a present R&D activity.

Questions

PwC clients that have questions about this In brief should contact their engagement partners.

Engagement teams that have questions relating to IFRS should contact Mary Dolson (44 (0)207 804 2930) or Ruth Preedy (44 (0)207 213 2123). Engagement teams that have questions relating to US GAAP should contact Karen Young (973.236.5648), John Hayes (973.236.4452), Pamela Yanakopulos (617.530.5163), or Mark Barsanti (617.530.6374).