Ihre Ansprechpartner

Sehr geehrte Damen und Herren,

für Rückfragen zu der beigefügten Publikation „In brief“ zur Thematik „Research and development funding arrangements: Accounting under IFRS“‘ stehen Ihnen folgende Ansprechpartner gerne zur Verfügung:

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In brief
A look at current financial reporting issues

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Research and development funding arrangements: Accounting under IFRS

Background

Over the past 20-30 years there have been many dramatic advances in medical and biological science. These advances have led to the development of newer, more sophisticated drugs with fewer side effects. With such complex science, the development path is often unpredictable and costly. While some products are successful, many more fail along the way. In many cases, promising compounds or new technologies fail to reach the market because companies have lacked access to adequate financing sources or have been forced to make difficult capital allocation decisions.

Despite dramatic advances in science and technology, established pharmaceutical and life science companies are faced with a number of challenges including:

- Blockbusters losing patent protection which leads to dramatic declines in sales and overall returns on invested capital;
- Traditional research methods do not always result in the same level of returns historically experienced in the industry with many companies suffering from dwindling research productivity and product pipelines as a result; and
- Dramatic shifts in what the public and regulators expect from new drugs and bringing a new drug to market is more difficult and costly than ever before.

In recent years these challenges have led to thousands of partnerships, strategic alliances and collaborations. Major pharmaceutical companies have employed these strategies for growth, and their business development professionals are always on the lookout for new opportunities. The demand for new sources of capital has also led to many companies exploring innovative R&D funding arrangements with various partners or investors (who often times may be financial/passive investors) to assist in development funding and to share the financial risks and rewards of the R&D efforts.

The purpose of this Alert is not intended to provide an “answer key” on the accounting and financial reporting complexities often associated with these structures. Rather, it should serve as a primer on the accounting standards that typically apply to such structures, including several examples meant to illustrate how one may apply the guidance to common structures observed in the market.

Issue

R&D funding arrangements between pharmaceutical companies (hereafter referred to as 'Pharma' but is also meant to encompass biotech, medical device and other life sciences companies) and financial investors are often very complex and can last for many years over the different phases of a product's life cycle - all the way from an early stage development project through to a marketed product. Differing levels of risk and reward may be transferred between parties depending on the stage in a product's life cycle that an agreement is signed. At one end of the spectrum, an arrangement might involve only the provision of debt financing for R&D with a well-defined obligation for repayment. Whereas, at the other end of the spectrum, a transaction might involve risk sharing between parties and encompass interrelated components including new legal entities, put and call options, debt and equity or other instruments, and/or royalty arrangements.

When negotiating these arrangements, Pharma and financial investors often have competing priorities.

Pharma Company	Financial Investor
• Target return on investment is usually lower than financial investor	• Typically target a high return on investment (often 30% and higher)
• Income statement benefit from funding via reduction of R&D expense or allocation of losses to other investor through non-controlling interests	• Seek to reduce risk by including a portfolio of products in the arrangement ("the basket approach") or have substitution rights to replace failed compounds
• Participation in Steering Committee and involvement in R&D	• Employ certain strategies to minimize cost of capital
• Ability to retain or regain ownership to provide top line revenue growth	• Exit strategy contemplated at inception

These competing priorities have resulted in companies exploring diverse funding structures with varied terms and conditions, which often lead to significantly different financial reporting outcomes. Each arrangement is unique and many contain various complex elements. There is no 'one size fits all' solution or a pre-packaged R&D funding strategy. Rather each agreement should be evaluated on its own merits and the accounting and financial reporting should reflect the substance and commercial reality of the arrangement.

The accounting framework used by the entity may make a substantial difference in the financial reporting consequences of the arrangement. Although US GAAP and IFRS are converged in many aspects, these arrangements touch areas where the standards have significant differences, particularly in accounting for liabilities and consolidation of structured entities. This alert addresses IFRS only; a companion alert that covers the same areas for US GAAP is available (US Pharmaceutical and Life Sciences Industry Alert 2014-4).

Key accounting issues and relevant IFRS guidance

These arrangements all include the funding party providing cash to execute research and development activities. There are three overarching accounting questions that arise; as follows:

- Does the funding result in recognition of a liability and if yes, a financial liability or a provision?
- If not a liability, then how is the cash received presented in the profit and loss account and in what periods?
- If a separate entity is created or used, what are the key factors to consider when determining if Pharma needs to consolidate the entity?

IFRS are often described as 'principle based' standards; it may be more accurate to say that IFRS are more broadly written and contain few exceptions and little or no industry specific guidance. The broad requirements of the standards on financial instruments and consolidation apply, without any special relief, to R&D funding arrangements. The application of the standards and the related accounting issues are discussed below.

Does the funding result in the recognition of a financial liability or a provision?

A financial liability, under IAS 32, '*Financial Instruments: Presentation*', is any liability that is a contractual obligation to deliver cash or another financial asset to another entity. In addition, a financial liability may be created indirectly if an entity can only avoid delivering cash or another financial asset by settling a non-financial liability.

For example, some funding structures allow Pharma to use its discretion to determine whether R&D should continue on the specified compound. However, if R&D is halted prior to the Investor achieving its return (for example, prior to regulatory approval), then Pharma must transfer the rights of the specified IP to the Investor. Pharma's ability to avoid cash repayment only by relinquishing rights to IP means a financial liability exists.

A requirement for the entity to deliver cash or another financial asset only if certain events occur or contingencies are resolved (contingent settlement provisions) is still likely to be a financial liability. Contingent settlement provisions will affect the measurement at initial recognition and subsequently, but they do not prevent recognition of a financial liability.

For example, if payment is required upon the occurrence or non-occurrence of uncertain future events that are beyond the control of both the issuer, Pharma, and the holder, Investor, the instrument will be classified as a financial liability. The issuer does not have the unconditional right to avoid delivering cash or another financial asset in this situation.

These conditions are seldom present in R&D funding arrangements. The Investor, while prepared to accept risk of failure, is seeking a positive return on their investment and will use different instruments and techniques to increase the likelihood of a positive outcome. The contingent settlement provision would not be a financial liability when Pharma has control of the contingency (that is, the power to avoid repayment) or the contingency is considered not genuine. However, this is rarely expected to occur in R&D funding arrangements.

Most R&D funding arrangements will either include a 'best development efforts' clause, have development decisions taken by another body such as a joint development committee or involve a portfolio of products. All of these may create the conditions for recognition of a financial liability because they increase the chances for

the Investor to get paid and tend to prevent the issuer from having control of the contingency.

A 'best development efforts' clause will require the pharma company, itself or through a CRO, to continue the development work until specified points of success or failure are reached. The pharma company will seldom be able to cease work or use the funds provided for other activity. Thus the contingency may be seen as out of their control; the work will be successful or unsuccessful without their discretion.

Development decisions that are taken by a joint development committee or even by the funding party are even more clearly outside the control of the pharma company.

A funding arrangement that involves a number of products may involve best efforts and or a joint development committee. The more products involved, the more likely that one will be successful, resulting in an increasing likelihood that the contingency will result in the payment of cash to the funding party.

Cash received under an R&D funding arrangement that results in recognition of a liability will almost always be classified as a financial liability under IAS 32 as the arrangements are invariably established by contract. Provisions, under IAS 37 '*Provisions, contingent liabilities and contingent assets',* are a residual category for liabilities that are not in the scope of another standard and are not executory contracts. It is unlikely that a funding arrangement would give rise to a provision under IAS 37.

If there is no liability, how is the cash received reflected in the income statement?

If the receipt of cash under a funding arrangement does not result in the recognition of a liability, the company should evaluate whether it is a service arrangement and over what period amounts should be recognised in the income statement. IFRS is not prescriptive on presentation and amounts should be presented as either revenue (top line) or as a reimbursement or contribution to research and development expenses (contra-development expense).

An entity recognises revenue from a transaction associated with the rendering of services, when the outcome of the transaction can be reliably estimated. This is the case when all of the following conditions are satisfied:

- The amount of revenue can be measured reliably;
- It is probable that the economic benefits associated with the transaction will flow to the entity;
- The stage of completion of the transaction can be measured reliably; and
- The costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

What are the key factors to consider when assessing consolidation if a legal entity is used?

An entity will consolidate all entities that it controls. Control requires power over relevant activities, exposure to variable returns and a link between power and returns under IFRS 10, '*Consolidated Financial Statements'.* Control assessments are straightforward for an entity controlled by voting rights. A structured entity exists when control is exercised by other means. The other means can include participating in the determination of purpose and design of the structured entity and asset selection, contractual arrangements, potential voting rights, contingent rights as well as power over activity that happens outside the structured entity but is relevant to it. An entity needs to consider whether it controls any entity in which it has an 'interest' or a 'special relationship', both of which are defined terms.

A new company or existing shell company (Newco) is frequently used in R&D funding arrangements. There are many varieties of entities used in funding arrangements and for a myriad of purposes. The entity may be owned by the investor or jointly owned by the investor and the pharma company. The pharma company may license or sell an existing compound or compounds in development to the Newco, the investor will provide funding and a joint development committee will oversee the work. The pharma company may provide limited or no funding at all. The development work may be undertaken by a CRO or may be contracted back to the pharma company itself. If development is successful, the investor earns a pre-established success based payment, often a multiple of the development spend.

Commonly observed features include options for the pharma company to buy back compounds or licenses if development work is successful or to buy the entire company, if only a single product is in the Newco. The investor may hold put options, exercisable on certain events. The effective outcome is that the investor is paid out on success. Call options, even if out of the money or only exercisable if contingent events occur, can give power to the holder under IFRS 10.

The broad nature of the consolidation guidance around structured entities and particularly around options would result in most project entities or Newcos being consolidated by the pharma company that originated the intellectual property and usually has options to re-acquire it on success.

Illustrative examples

The following examples look at various R&D funding structures that have been observed or proposed in the market:

Example 1 — Funded R&D Structure

Facts: An unrelated financial investor partners with Pharma for the development of selected compounds which are in phase II. No new legal entity is created. The financial investor commits up to a specified Euro amount to fund the R&D of a portfolio of pre-selected compounds. The financial investor will receive lump sum payments on regulatory approval of any of the compounds and royalties on future sales of the compounds in the portfolio. The financial investor will not receive any repayment if compounds are not successfully developed. The financial investor has agreed the compound selection and the overall development plans and budgets but does not participate in any of the development or commercialization activities. Pharma must use its best efforts to execute the development plans until regulatory approval or demonstration of failure.

Analysis: The arrangement gives rise to a financial liability in the scope of IAS 32. It is not an executory contract as the financial investor has no performance obligations. The amount and timing of payment is contingent on the occurrence of future events that are outside the control of either party. The cash received is recorded as a liability. The liability is subsequently re-measured through the income statement at each future reporting date under IAS 39.AG8. If all of the compounds fail, any remaining liability is derecognized and reclassified to the income statement as a contra-expense.

Example 2 — Newco Structure

Facts: An unrelated financial investor capitalizes a Newco in exchange for 100% of the equity in the Newco. The Newco licenses a portfolio of in-development (Stage I – III) products from Pharma. Pharma holds a call option to purchase 100% of Newco equity at a price based on a multiple of financial investor's invested capital. The option is exercisable any time during a 3 year period commencing 1 year after the transaction close. Pharma also holds a series of call options over the individual compounds if certain development milestones are met. The call options are priced at a multiple of actual development expenditure. Pharma and/or others provide R&D or CRO services for Newco at a rate consistent with market prices.

Analysis: Pharma has a special relationship, as set out in IFRS 10, with the Newco which qualifies as a structured entity. Pharma needs to determine whether it has control of the Newco and needs to consolidate it. Pharma has control if it has power over relevant activities and exposure to variable returns. The consolidation analysis can be complex. The financial investor may own all of the equity but this is less relevant as structured entities are seldom controlled through straightforward voting rights. Pharma needs to consider its role in determination of the purpose and design of Newco, the impact that asset selection will have on the ultimate success of Newco, its ability to 'claw back' individual compounds or the entire entity for a fixed price if development is successful.

The Newco may lack substance; for example it may have no employees, facilities or ability to perform the required R&D on its own. Typically, these activities are performed by Pharma through a services contract, through which a certain level of decision making resides. The other important decisions around which compounds will be included in the portfolio and the development plan are generally pre-determined or under the direction of a steering or joint development committee on which Pharma will be represented.

An arrangement where the funds contributed by the financial investor are genuine equity may result in a 'P&L neutral' outcome for the Pharma, even if it consolidates Newco. On consolidation, Pharma would recognise the funds spent by Newco on R&D funding within R&D expense. However, losses from R&D and other expenses of the Newco would be allocated to 'non-controlling interests' to the extent of the financial investor's interest in Newco.

Example 3 — Substantive R&D Partnership

Facts: An unrelated R&D partner capitalizes a Newco in exchange for 100% of the equity of the Newco. The Newco is staffed by a team of qualified doctors, scientists and technicians who have significant expertise in drug development and enters into a collaboration arrangement with Pharma to develop certain compounds that are owned by Pharma. Newco funds and conducts the development activities and will own the rights to the data derived from the development activities. A Joint Development Committee is established to control the operations of the Newco with the Pharma and Newco having equal representation. Pharma and/or others (for example, external CRO) provides R&D services for Newco at rates consistent with market prices. Upon the occurrence of certain predetermined 'success' milestones, Pharma is required to acquire 100% of the equity in Newco for a fixed price of 2x the capital invested by the financial investor. Pharma has no obligation if the R&D is not successful and the milestones are not met.

Analysis: The consolidation considerations are similar to those discussed in the previous example. Economically the 'offer' to provide development services for a service fee is priced on the estimated development costs plus a risk premium for a negative study result. However, Pharma does not have sole power over the development work because the JDC decides about the continuation of the development project. Pharma has the obligation to pay 2x the development costs to the partner and has no option to avoid this payment if the compounds achieve the milestones. The partner is acting, effectively, as a service provider under predetermined conditions. The funding provided is likely to be a financial liability with a contingent settlement provision and a predefined payback structure.

The financial liability with a contingent settlement provision to the partner consists of two components; the reimbursement of development expense and a risk premium. The reimbursement component would be accounted for as a financial liability because Pharma has no influence on the decision to stop the development project. The liability would be measured at least at the cash amount received because the probability of success within a study cannot be reliably measured. Generally, the development data will have no alternative use for the partner, Pharma might have to report all development costs as own development expenses. Any liability recorded for funding received that relates to the reimbursement of the development expense component could be reversed as contra-development expense upon development work being abandoned prior to approval.

The premium component of the contingent settlement provision should be recognized at fair value as funding is received and disclosed as a contingent financial liability. The premium may be recognized at the net present value as expense if uncertainty of the study results is resolved. Any liability recorded for the risk premium component may be reversed as contra-expense upon development work being abandoned prior to approval through the same line item that it was previously recorded.

R&D funding arrangements are always complex and require assessment of several judgmental areas of the accounting literature. Each arrangement should be evaluated based on the specific facts and circumstances of that arrangement and the substance of the underlying economics.

Questions

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