Research and Development (R&D) Funding Arrangements

Background
Over the past 20-30 years, there have been dramatic advances in medical and biological science. In many cases, promising compounds and new technologies fail to reach the market because companies lacked access to adequate financing sources or were forced to make difficult capital allocation decisions.

Despite dramatic advances in science and technology, pharmaceutical companies (hereafter referred to as “Pharma” but also meant to encompass biotech, medical device and other life sciences companies) are faced with a number of challenges that have led to the formation of R&D focused partnerships, strategic alliances and collaborations. Major pharmaceutical companies have employed these strategies for growth, and as a result, their business development professionals are frequently evaluating 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.

Arrangements between Pharma and financial investors have become more prevalent in recent years. When negotiating these arrangements, Pharma and financial investors often have different priorities.

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<thead>
<tr>
<th><strong>Pharma Company</strong></th>
<th><strong>Financial Investor</strong></th>
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<tbody>
<tr>
<td>Minimize cost of capital</td>
<td>Typically expects a high return on investment</td>
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<td>Income statement benefit from funding that shares R&amp;D expense with investors or attributes net losses to non-controlling interests</td>
<td>Reduce risk by increasing the probability of return of capital, e.g., by including a portfolio of products or by obtaining substitution rights that allow replacement of failed compounds with new candidates</td>
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<td>Control of Steering Committee and direction of R&amp;D</td>
<td>Protective governance rights and/or termination rights</td>
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<tr>
<td>Ability to retain or regain ownership of intellectual property to provide top line revenue growth</td>
<td>Exit strategy contemplated at inception</td>
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These differing priorities have resulted in Pharma exploring funding structures with varied terms and conditions. There are two common R&D strategies that are the main focus of this Alert, briefly described as follows:

- **Direct R&D Funding**: This strategy is predicated on a financial investor providing direct funding to Pharma for specified R&D projects in return for future payments (e.g., milestone payments, royalties on sales) contingent upon successful completion of the R&D.

- **NewCo R&D Funding**: This strategy involves a third-party investor establishing a new entity to perform the R&D, which may be outsourced back to Pharma or to an unaffiliated contract research organization (“CRO”), often with a predetermined exit (e.g., providing Pharma a call option or contingent forward purchase) only upon successful completion of the R&D.

The purpose of this Alert is not to address all possible accounting and financial reporting complexities associated with these R&D structures. Rather, it is intended to serve as a primer on the accounting principles that typically apply to such structures. We also provide several examples meant to illustrate how that guidance may be applied to some of the more common structures observed in the market. Each arrangement is unique and many contain complex elements as well as facts and circumstances underlying the R&D project that may impact the accounting and financial reporting for the arrangement.

### Issue

R&D funding arrangements between Pharma and financial investors are often very complex and can last for many years. Arrangements may extend over different phases of a product’s life cycle—from early stage development to the marketing of a finished product. Different levels of risk and reward may be transferred between parties depending on the stage in a product’s life cycle in which an agreement is established. 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. At the other end of the spectrum, a transaction might involve R&D risk sharing between the parties and encompass complex components, such as new legal entities, put and call options on an entity’s equity or intellectual property, debt or equity instruments, and royalty arrangements. There is no “one size fits all” solution or a prepackaged R&D funding strategy. Rather, each arrangement should be evaluated on its own merits by considering its unique facts and circumstances to determine the accounting and financial reporting impacts, which should ultimately reflect the substance and commercial reality of the arrangement.

Although U.S. GAAP and IFRS are converged in certain respects, the accounting for R&D arrangements is an area with significant differences, particularly with regard to the accounting for liabilities and the consolidation of structured entities. This Alert addresses only U.S. GAAP considerations. A companion Alert that addresses the accounting for IFRS reporting entities is available.

### Key accounting issues and relevant guidance

R&D funding arrangements typically involve the funding party or investor providing cash to fund research and development activities. The overarching accounting questions that arise in these cases are as follows:

- **Direct R&D Funding**: Does the funding result in recognition of a liability by the recipient, and if so, is it recognized as a financing obligation or as deferred income/revenue?

- **NewCo R&D Funding**: If a separate entity is created or used, what are the key factors to consider when determining if the entity should be consolidated?
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R&D Funding Arrangements (continued)

Direct R&D Funding: Does the funding result in the recognition of a liability?

Step 1: Determine whether the arrangement falls under the scope of ASC 730-20, Research and Development Arrangements

When evaluating the accounting model for these arrangements (particularly in situations where a new legal entity is not established), Pharma should assess whether the arrangement is within the scope of ASC 730-20, Research and Development Arrangements, or ASC 470-10-25, Sales of Future Revenues. ASC 730-20 (or “the funded R&D guidance”) provides guidance on the accounting by an entity that is a party to an R&D arrangement in which it can obtain control of the results of R&D that is funded partially or entirely by others. ASC 470-10-25 (or “the sales of future revenues guidance”) provides guidance on the accounting by an entity that receives a payment of cash from an investor and in exchange, agrees to pay the investor a specified percentage or amount of revenue for a particular product line, business segment, trademark, patent, or contractual right for a defined period of time.

To determine which guidance an arrangement falls under, Pharma must first evaluate the nature and substance of the risk associated with the stage of development of the compound or new technology. Generally, the funded R&D guidance should be applied if the R&D risk is substantive and it is not yet probable that the development will be successful. However, if an entity determines that successful completion of the R&D is probable at the time the funding is received, it should follow the sales of future revenues guidance.

Certain funding arrangements that incorporate other significant risks (including legal, business, operational, time-to-market, etc.) should be carefully evaluated to determine the applicable literature. For example, if the predominant risk to the third party investor’s ability to recoup its investment relates to the outcome of patent litigation, it may not be appropriate to evaluate the arrangement under the funded R&D guidance. If Pharma determines that an arrangement falls within the scope of the sale of future revenue guidance, the funding received from the financial investor would be characterized as either deferred revenue or as a financing obligation. The sales of future revenues guidance includes several criteria that would be considered when making such determination.

Step 2: If the arrangement is within the scope of the funded R&D guidance, determine if it is in substance an obligation to perform contractual R&D services or a liability to repay the funding party

The funded R&D guidance requires an entity to determine the nature of the obligation it incurs when it enters into an R&D funding arrangement. In particular, the guidance requires consideration of whether that obligation is (1) a liability to repay the funding party or (2) an obligation to perform contractual services. In order to conclude that a liability does not exist, the transfer of financial risk associated solely with R&D from Pharma to the financial investor (or other counterparty) must be substantive and genuine. The key is to determine who bears the risk of R&D failure and whether Pharma is obligated to repay any of the funds regardless of the outcome of the research and development. That is, consider whether the financial investor will be repaid some or all of its investment even if the R&D project is not successful.

The transfer of financial risk associated with R&D may not be genuine if Pharma is committed to repay any of the funds provided by the other parties regardless of the outcome of the R&D. Examples in which the entity is committed to repay include:

- Pharma guarantees, or has a contractual commitment that assures repayment of the funds provided by the financial investor regardless of the outcome of the R&D
The financial investor has rights to substitute compounds if the initial compound is not successful and such substitution provides the financial investor with the ability to recoup some or all of its funding.

The financial investor can require Pharma to purchase their interest in the R&D regardless of the outcome.

The financial investor automatically receives debt or equity securities of the entity upon termination or completion of the R&D regardless of the outcome.

Investors or collaborative partners providing the funding in these arrangements generally attempt to reduce their risk of loss. One approach is to include multiple product candidates in the arrangement (“the basket approach”). Increasing the number of product candidates covered by the arrangement provides diversification for the investor or collaborative partner and may reduce financial risk by providing more “at bats” for successful completion of an R&D project and associated return of investment. Arrangements that include a basket of products are more difficult to evaluate because the basket may (i) include products where successful completion of the R&D is probable, or (ii) substantially mitigate the investor’s financial risk by increasing the aggregate likelihood of repayment (commonly referred to as the “portfolio effect”). A product candidate that is probable of successful completion or a basket of products that, in the aggregate, provide for the probable successful completion of at least one product based on the portfolio effect, would likely cause the arrangement to be outside the scope of the funded R&D guidance. One product in the basket that is probable of completion may be sufficient to require that the entire arrangement be accounted for under the sales of future revenues guidance.

In cases where no product candidate in the basket is probable of successful R&D completion, companies should evaluate the number of products in the arrangement, the stage of development of each product, and the correlation between each product (e.g., whether the R&D success of one product impacts probability of success of another, such as if dealing with additional indications of an approved compound). Companies should also evaluate the terms for measuring the level of investor payout both for the individual products and in aggregate for the entire portfolio. These features can complicate the analysis of whether a transfer of substantive R&D risk to the financial investor has occurred and/or whether Pharma has an obligation to repay funds regardless of some of the R&D outcomes, which could ultimately require liability accounting.

Although R&D funding arrangements may not include contractual provisions that require the company to repay any of the funds, conditions might indicate that the company is likely to bear the risk of failure of the R&D. If it is probable that the company will repay any of the funds regardless of the outcome of the R&D, the accounting should be based on the presumption that the company will repay the counterparty. Examples of conditions leading to the presumption that the company will repay the counterparties include any of the following:

- The company has indicated its intent to repay all or a portion of the funds provided regardless of the outcome of the R&D
- The company would suffer a severe economic penalty if it failed to repay any or all of the funds provided to it regardless of the outcome of the R&D
- A significant related party relationship (when 10% or more of the entity providing the funds is owned by related parties) between the company and the party funding the R&D exists at the time the company enters into the arrangement
- The company has essentially completed the project before entering into the arrangement

The R&D guidance does not address the income statement classification of R&D funding accounted for as an obligation to perform contractual services. For further discussion about...
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income statement classification, refer to Alert 2010-4: Accounting for Funded Research & Development Arrangements.

NewCo R&D Funding: What are the key factors to consider when assessing if the legal entity should be consolidated?

While a separate legal entity is typically not required, many of the more innovative arrangements appearing in the market involve the formation of a new entity (“NewCo”) to facilitate an R&D funding arrangement. In these situations, companies with an interest in a NewCo would evaluate whether they are required to consolidate the entity under the guidance in ASC 810, Consolidation, and whether they are still subject to the funded R&D guidance in situations where the financial investor’s equity investment is not considered substantive.

In NewCo R&D structures, the NewCo is typically owned 100 percent by the financial investor. Pharma may participate on the Board of the NewCo, or on a steering committee, and may also provide R&D services. Often Pharma will have a call option allowing it to acquire approved products from NewCo.

The key issue is whether Pharma should consolidate the NewCo. This analysis often hinges on which party has the power/control, through voting or other contractual rights, over the most significant activities of NewCo. The analysis of which party is ultimately making the most important decisions of NewCo is complex and judgmental. Steering or joint development committees are typically set up to facilitate decision making over the operations of the entity. Often one party is responsible for all decisions regarding the activities through the FDA approval process, whereas another party may be responsible for all significant activities post FDA approval, including manufacturing, marketing and distribution of the product. Careful consideration is required to determine the “most significant activities” as they may change depending on the product candidates’ stage of development. Because financial investors are generally passive, there is often a presumption that Pharma controls the activities and therefore consolidates NewCo. Accordingly, one of the most important aspects of the analysis is to evaluate whether the involvement of the financial investor is substantive. This includes evaluating the management and employees hired to run the operations of NewCo and whether these parties are independent of Pharma and have the appropriate understanding of the products in order to unilaterally make effective operating decisions for NewCo.

Another important aspect of the consolidation analysis includes confirming that decisions are not “hard wired” or predetermined at formation, such that NewCo’s owners do not have substantive decision-making rights. If that were the case, generally Pharma and not the financial investor would be considered to have control and therefore would need to consolidate NewCo.

If a party consolidates an entity in which its equity ownership is less than 100 percent, then the portion of the entity’s equity not owned will be presented as non-controlling interest. Companies are required to present net income (loss) and comprehensive income (loss) attributable to the parent and the non-controlling interest on the face of the applicable consolidated financial statements. If Pharma does not own an equity interest in, or otherwise share in the operating performance of the entity through contract and consolidates the newly created R&D entity, then the income or loss of the entity will be attributable to the non-controlling interest holder in Pharma’s consolidated income statement. However, Pharma must also evaluate the implications of any terms of the arrangement that may allow or require it to redeem the non-controlling interest. These features may result in the non-controlling interest being classified either as a liability or as “temporary” equity on the balance sheet, which may have a dilutive impact on EPS.
Illustrative Examples

The following examples illustrate several R&D funding structures that have been observed or proposed in the market:

Example 1 — Direct R&D Funding Structure

Facts: An unrelated financial investor partners with Pharma for the development of a selected compound which is in phase II. Funding is paid directly from the investor to Pharma (i.e., no separate legal entity is created). The financial investor commits up to a specified dollar amount to fund the R&D for the preselected compound. At inception, successful development of the compound is not yet probable. The financial investor will receive a lump sum payment only upon regulatory approval of the compound and royalties from future sales of the compound if and when it is commercialized. The financial investor will not receive any repayment if the compound is not successfully developed. The financial investor has agreed with Pharma on the selection of the compound and the overall development plan and budget, but does not participate in any of the development or commercialization activities. The agreement requires Pharma to use its best efforts to execute the development plan until regulatory approval or demonstration of failure.

Analysis: Given the nature of the development and regulatory process, the activities undertaken as part of the project meet the definition of research or development in ASC 730-10-20. Based on the current phase of development, Pharma has concluded that R&D risk is substantive at the time the arrangement is initiated (because successful development of the compound is not probable). The analysis should be supported by internal data as well as the project’s probability of technical and regulatory success (“PTRS”) or similar assessment. Accordingly, Pharma should apply the R&D guidance to determine whether the funds received represent a liability to repay the financial investor or an obligation to perform contractual services.

To conclude that a liability does not exist, the transfer of risk involved with the R&D from Pharma to the investor must be substantive and genuine (i.e., it must not be probable that any of the funds would be repaid regardless of the outcome of the R&D).

In the fact pattern described above, Pharma has no explicit or implicit obligation to repay any of the funds and there are no substitution rights or other arrangements that effectively require Pharma to repay any of the R&D funds. As a result, Pharma would likely conclude that the arrangement is an obligation to perform contractual services. Depending on the specific facts and circumstances of the arrangement and Pharma’s accounting policy for similar transactions, the funding received may be reflected in the income statement as either revenue, other income, or as an off-set to R&D expense.

Example 2 — Consolidated NewCo Structure

Facts: An unrelated financial investor capitalizes DrugCo with cash in exchange for 100 percent of the equity in DrugCo. Pharma provides access rights to DrugCo for a phase II compound currently in development (and not considered probable of regulatory approval at the time the arrangement is initiated). Pharma has a call option that permits purchase of 100% of DrugCo if certain development milestones are met. The call option exercise price is based on a multiple of actual development expenditures. The financial investor remains in a passive role...
and has not appointed board members or hired any employees that have the technical or commercial expertise to make the most important decisions during the development process. Pharma and/or others provide R&D or CRO services for DrugCo at billing rates consistent with market prices.

Analysis: The assessment generally begins with analyzing whether Pharma would be required to consolidate DrugCo. The consolidation analysis requires judgment, and often hinges on whether Pharma has the ability to direct decision making at DrugCo. In arrangements such as the one described above, DrugCo often lacks substance in that there are no employees, facilities or ability to perform the required R&D. Typically, these inputs are provided and activities are performed by Pharma through a non-cancellable services contract, which conveys to Pharma a significant level of decision making authority. The other important operating decisions at DrugCo, including the compound’s development plan, are generally predetermined or under the direction of the steering (or joint development) committee, which is typically controlled by Pharma. As a result of the passive nature of the financial investor, the nature of decisions predetermined by Pharma, and the power embedded within the services contract, the power over key decisions likely remains with Pharma and would likely result in Pharma’s consolidation of DrugCo. Additionally, for structures with call options that allow a purchase of DrugCo, Pharma should assess whether a currently exercisable, in-the-money option would effectively provide it with control.

Arrangements like the one described above are often undertaken because in some circumstances, they can lead to a “P&L neutral” outcome, even if DrugCo is required to be consolidated. If DrugCo is consolidated, Pharma would recognize the funds spent by DrugCo on R&D within its consolidated R&D expense; however, the net loss (or income) of DrugCo would be attributed to the non-controlling interests (“NCI”) to the extent of the financial investor’s ownership interest in DrugCo (100 percent in this example).

If the financial investor’s equity investment was not substantive, or included certain characteristics of a liability, the result may not be neutral to Pharma’s consolidated net income or loss. If the funds meet the definition of a liability under ASC 480, as would be the case when the investor has a date-certain redemption or put right for its ownership interest in DrugCo, there would be no attribution of DrugCo’s net income or loss to the NCI in Pharma’s consolidated financial statements. If temporary equity classification of the NCI is required by ASC 480-10-S99, which may be the case if the investor could elect to “put” their equity interest to Pharma, the attribution of net income or loss to NCI in Pharma’s consolidated financial statements could be impacted depending on the nature and terms of the underlying ownership interests.

When evaluating arrangements like the one described above, DrugCo should consider the funded R&D guidance to assess whether the investor’s equity investment is substantive. If not, liability classification may be required. For example, arrangements where Pharma is obligated to purchase the equity of DrugCo (or all of the assets of DrugCo) or if DrugCo’s right to the licensed compound lasts only for a finite period of time and then reverts back to Pharma, may not represent a transfer of substantive and genuine R&D risk. In these cases, the funding may need to be recorded as a liability under the funded R&D guidance. In the example above, Pharma holds a call option to purchase the equity in DrugCo, but is not required to exercise the option if the compound is not successfully developed. In this circumstance, transfer of the R&D risks and any rewards of the compound to the financial investor may be substantive because if Pharma does not exercise its call option, the financial investor would retain its ownership in the compound and would be exposed to all risks and rewards of ownership.

It is also important to note that there are accounting and financial reporting implications if and when Pharma re-acquires the R&D by exercise of the call option. Implications would include:
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- EPS—acquisition of the NCI at a price greater than fair value may impact EPS as a deemed dividend;
- The financial reporting impact of requirements to make future purchase consideration payments (often the exercise price for the call will include up-front cash, milestone payments or ongoing royalties or some combination thereof); and
- Disclosure—financial statements should include transparent disclosure of the existence of these types of arrangements and the impact, if significant, of exercising the call.

Example 3 — Substantive R&D Partnership

**Facts:** An unrelated R&D partner capitalizes DevelopCo in exchange for 100 percent of the equity of DevelopCo. DevelopCo is staffed by a team of qualified doctors, scientists and technicians who have significant expertise in drug development. DevelopCo enters into a collaboration arrangement with Pharma to develop certain compounds that are owned by Pharma. Under the collaboration agreement, DevelopCo licenses the intellectual property underlying the compounds from Pharma. DevelopCo funds and conducts the development activities and will own the rights to all data derived from the development activities. A joint development committee (JDC) is established to control the operations of DevelopCo, with Pharma and the unrelated partner having equal representation. Pharma and others (e.g., external CRO) provide R&D services for DevelopCo at rates consistent with market prices. Upon regulatory approval of a compound, Pharma is required to acquire that compound from DevelopCo for a fixed price of 2x the actual development expenditures for that compound. Pharma has no obligation to acquire any compound where regulatory approval is not obtained.

**Analysis:** Similar to Example 2, Pharma must evaluate whether it would consolidate DevelopCo for financial reporting purposes. Whereas in Example 2 the financial investor was passive and Pharma made all key operating decisions, the partner in the DevelopCo structure above provides the entity with employees that have drug development expertise. In this situation, the partner and DevelopCo have qualified experts in the development field capable of participating in the decisions that most significantly impact the performance of the entity. When evaluating which party, if any, would consolidate DevelopCo, the decision making power of the JDC and the extent of any upfront or predetermined decisions should be considered. Examples of significant decisions that would likely factor into the analysis may include: selection of the compounds to be developed, the initial development plan and budget, and the initial selection of the service provider (e.g., CRO or Pharma), among other decisions.

Pharma’s obligation to purchase the compounds if successfully developed by DevelopCo is a contingent forward purchase obligation, which would likely not provide Pharma with effective control of DevelopCo or the individual compounds until the contingent milestones have been met. To the extent the substantive decision making has been ceded to the JDC or more broadly to the R&D partner, Pharma may conclude that it should not consolidate DevelopCo. However, Pharma may need to recognize a liability for the contingent forward contract. Specific facts and circumstances would need to be evaluated by Pharma to make the appropriate recognition and measurement determinations.

It is also important to note that there are accounting and financial reporting implications if and when the contingent forward is triggered and the approved compound is reacquired. Among other issues, Pharma would need to assess whether the purchase of a compound represents an asset acquisition or a business combination. For further discussion on distinguishing between asset
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acquisitions and business combinations, refer to Alert 2013-3: Distinguishing a Business from an Asset or a Group of Assets.

Questions

R&D funding arrangements are often 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.

PwC clients that have questions about this Industry Alert should contact their engagement partners. Engagement teams that have questions should contact Karen Young (973.236.5648), Brett Cohen (973.236.7201), John Hayes (973.236.4452), Matt Sabatini (646.471.7450), Pamela Yanakopulos (312.298.3798), or Joe Jennings (646.471.2409).