Stay Informed: Pharmaceutical and Life Sciences Industry GAAP Alerts

2013-3

Distinguishing a Business from an Asset or a Group of Assets

Background

Pharmaceutical, biotech, medical device and other life sciences companies frequently deal with the highly judgmental and complicated area of determining whether an acquisition, investment or license should be accounted for as a business combination or an asset acquisition. This distinction matters as the accounting for a business combination varies significantly from the accounting for an asset acquisition, particularly in the pharmaceutical and life sciences industry. This is in large part due to the fact that in-process research and development ("IPR&D") is capitalized in a business combination, but expensed in an asset acquisition if the IPR&D has no alternative future use. Other accounting differences can occur as well. Appendix A highlights some of the key acquisition date and post-acquisition accounting differences between a business combination and an asset acquisition.

Oftentimes, arrangements that on the surface appear to convey only assets, include other elements that, for accounting purposes, may mean they meet the definition of a business. This could be the case for acquisitions of intellectual property or other assets or in-licenses of intellectual property. The business combinations guidance can lead to many transactions being considered businesses, including many early-stage projects or in-licenses that grant the licensee rights to inputs and processes.

To assist in determining whether a company has acquired a business, it is helpful to consider the definition of a business provided in the business combinations guidance:

> *"A business is an integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants. A business consists of inputs and processes applied to those inputs that have the ability to create outputs. Although businesses usually have outputs, outputs are not required for an integrated set to qualify as a business... However, a business need not include all of the inputs or processes that the seller used in operating that business if market participants are capable of acquiring the business and continuing to produce outputs, for example, by integrating the business with their own inputs and processes."*

This definition is important because it helps emphasize why it is often challenging to assess whether an acquisition of an entity, an asset, a group of assets or in-licenses of intellectual property constitutes a business. Specifically, a business only needs inputs and processes, not outputs.

Examples of inputs include intellectual property, the ability to obtain access to necessary materials or rights and a workforce. Examples of processes include a system or standard that when applied to the input, can create the output. This may include strategic management processes, operational processes and resource management processes, some of which may be inherent in employees retained following the acquisition.

Additionally, a company buying an entity, an asset, a group of assets or in-licensing intellectual property does not need to acquire all of the inputs or processes that the counterparty used in operating that particular business for it to still be considered a business combination as long as the missing elements can be replaced by market participants (e.g., by integrating the business with their own inputs and processes). The easier it is to obtain the missing elements in a relatively short time period, the more likely the set of assets and activities are a business.

Issue

When companies consider whether an acquisition of an entity, an asset, a group of assets or an in-license should be accounted for as an asset acquisition or a business combination, it is important to identify all elements of the acquired group, including inputs, processes and/or outputs of the acquired group. An assessment of what is included in the acquired group will determine whether the acquired group has the capability to produce outputs and whether any elements that are missing from the acquired group would impact a market participant's ability to produce outputs. In fact, sometimes it is helpful to identify all of the elements of a business that have not been acquired as a means of considering whether those elements could be readily replaced or replicated by a market participant.

Some relevant factors to consider in determining whether a business has been acquired include the following:

- *Stage of development*: What is the stage of development of the acquired assets? The earlier in the development stage, the lower the likelihood that there are inputs or effective processes that are capable of providing a return in any substantive form (for example, a compound in the pre-clinical phase by itself would often not yet be capable of creating outputs). As the intellectual property moves further along in the development lifecycle, the more probable it becomes that there are substantive inputs as well as one or more processes. However, even licenses of rights to develop and manufacture intellectual property in the pre-regulatory approval stage or acquisitions of development stage companies can be businesses.
- *Developed technology*: If developed technology is being acquired, consider how the developed technology was operated by the seller, including how it was manufactured, promoted and distributed. Are any of the other inputs and processes also being acquired? If not, does the buyer have access to those inputs and processes (for example, via hiring the seller or other parties to perform services)? In many cases, a buyer may be acquiring more than just the rights to developed technology and often may acquire inputs such as inventory, customer lists and other assets. Generally, if developed technology is acquired with some of these additional inputs and/or processes, the acquired set is likely a business.
- *Customers*: If the acquired group includes a customer list, consider whether these inputs can be combined with other acquired inputs and/or processes to generate an output. For example, if the buyer acquires intellectual property and a customer list, then it may be capable of selling the product underlying the intellectual property even if it does not acquire

a sales force. As long as it has inputs (intellectual property and a customer list) and processes (the right and ability to manufacture and distribute), the acquired group is likely capable of generating outputs. If the acquired group includes customer relationships, those relationships were likely established by selling an output to those customers. Therefore, it is likely that processes and inputs have also been acquired with the customer relationship and that a business has been acquired.

- *Employees*: It is important to understand if the buyer will employ any of the seller's former employees. If so, understanding the employees' functions and skill level and what they will be engaged to do will assist in the assessment of whether the acquired group constitutes a business. For example, employees involved in administrative and clerical processes, such as accounting, billing and payroll, typically would not be functioning in processes that are used to create outputs. On the other hand, retention of employees who are crucial to future development of a compound (such as those with technical expertise or experience working with regulators, and/or employees who have relationships with customers or suppliers that are critical to the sale of the acquired assets) may indicate a business has been acquired. Even if the acquirer does not employ any of the seller's former employees, in some cases, the buyer may enter into a contract with the seller or other parties to secure critical services necessary to develop a compound. These services may be considered inputs or processes, which would suggest the acquisition is a business.

- *Manufacturing facilities*: If a buyer acquires a manufacturing facility and that manufacturing facility is validated and currently producing an FDA approved product, it is more likely that the purchase of the facility constitutes a business since it is capable of producing outputs using a manufacturing process. However, if there is a significant amount of effort and high risk associated with obtaining validation, the purchase may be considered an asset acquisition since the facility may not yet be capable of producing outputs on the acquisition date. This determination can require significant judgment and will depend on the specific facts and circumstances.

- *Contractual arrangements and outsourcing of key processes*: Consideration should be given to which contracts are assumed or entered into as part of the arrangement. These contracts may provide evidence that the buyer (and other market participants) can easily access inputs or processes that it did not acquire outright but, when combined with the acquired intellectual property, are capable of producing outputs. These types of outsourcing arrangements may include supply or manufacturing agreements (assuming the buyer has the right to manufacture), research and development contracts and contracts to lease property, plant or equipment that, when combined with the intellectual property, would be considered a business.

- *Inventory*: If the acquired group includes inventory for a product which is FDA approved, the acquired set most likely includes inputs and processes for producing the product. Therefore, a business has likely been acquired.

- *Assets or share acquisition*: Generally, acquiring the shares of an operating company (as opposed to a shell company) gives a buyer the opportunity to continue to run the company as it was operating before the acquisition. Although the acquirer may have different plans for operating the business going forward, if a market participant could operate the business as it was operating before the acquisition, then it likely meets the definition of a business.

- *Purchase consideration*: If it is apparent that goodwill is present in the acquired group, it should be presumed the acquired group is a business. However, the converse is not necessarily true (i.e., a business may not necessarily have goodwill in all cases).

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The factors listed above are intended to provide a framework for making the assessment of whether an acquired group is considered a business. However, the list is not meant to be all inclusive, nor is any one factor necessarily determinative. In addition, because U.S. GAAP and IFRS business combinations standards offer converged guidance when defining a business, the observations provided above and the following illustrative examples would apply equally to companies applying either U.S. GAAP or IFRS.

For more information on determining whether a transaction represents a business combination or an asset acquisition, please refer to *A Global Guide to Accounting for Business Combinations and Noncontrolling Interests,* PwC's comprehensive publication on accounting for business combinations under both U.S. GAAP and IFRS.

Illustrative Examples

The following examples provide practical illustrations of three different fact patterns related to the pharmaceutical and life sciences industry:

Example 1 — Acquisition of medical device that has been approved for marketing

Facts*:* Development Inc. recently received regulatory approval for a medical device. Development Inc. has not yet started selling the device but has already contracted with a third party to manufacture the device. Development Inc. employs research and development, regulatory and sales personnel who are focused on the approved medical device.

Med Device Co. purchases the approved intellectual property related to the device from Development Inc. and also assumes the manufacturing agreement with the third party. Med Device Co. does not hire any people from Development Inc. because it already has its own sales force and management team.

Analysis*:* Based on the facts above, Med Device Co. likely acquired a business. This is because it purchased the inputs in the form of the intellectual property rights to an approved medical device. The rights to the approved medical device inherently include a process for replicating the device design. Med Device Co. is not acquiring a manufacturing facility, but it assumed the third party manufacturing agreement, which gives it the process needed to manufacture the medical device. Although Med Device Co. did not hire any of Development Inc.'s employees, Med Device Co. and other market participants in the medical device sector have existing workforces with the scientific, regulatory and sales and marketing capabilities necessary to produce and sell outputs from the acquired right to the medical device.

Example 2 — In-license of intellectual property in Phase III clinical trials

Facts*:* Development Inc. owns the right to several pharmaceutical product candidates. Its only activities consist of research and development that is being performed on the product candidates. Development Inc. employs management and administrative personnel as well as scientists that are vital to performing the research and development. Big Pharma Co. licenses from Development Inc. the intellectual property rights to one of the product candidates that is in Phase III clinical trials. As part of the license, Big Pharma Co. is granted the development and manufacturing rights of the product candidate. Although Big Pharma Co. does not hire scientists to perform the research and

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development of the product candidate, it enters into an agreement with Development Inc. by which Development Inc. will provide research and development services directed at the product candidate.

Analysis*:* Based on the facts above, Big Pharma Co. likely acquired a business through its in-license of intellectual property. The in-license provided Big Pharma Co. the right to develop and manufacture the intellectual property (an input) which is in Phase III clinical trials and the right to access the documented processes and development work performed thus far (i.e., operating protocols and procedures established by the scientists). Therefore, Big Pharma Co. has control over the required elements of a business (i.e., inputs and processes). Although Big Pharma Co. did not acquire employees, it can easily access employees with critical knowledge of the product candidate through the research and development agreement with Development Inc. Further, Big Pharma Co. does not need equipment or other assets since Development Inc. will provide access to those assets via the research and development agreement.

While Big Pharma Co. did not acquire a manufacturing facility or a sales force, it does have the right to manufacture the intellectual property and it determined that the likely market participants are other large pharmaceutical companies that already have these items or could easily replicate them. Therefore, the inputs and processes obtained through the in-license arrangement are likely capable of producing outputs as the rights to commercialize the product candidate exist.

Example 3 — In-license of intellectual property in the pre-clinical stage

Facts*:* Assume the same facts as presented in Example 2, except Big Pharma Co. licenses from Development Inc. the intellectual property rights to one of the product candidates that is currently in the pre-clinical stage of development. No strategic management processes, operational processes or resource management processes existed for the product candidate at the date of the acquisition. Additionally, Big Pharma Co. did not enter into an agreement with Development Inc. to receive research and development services nor did it hire any of Development Inc.'s scientists or other employees.

Analysis*:* Based on the facts above, Big Pharma Co. likely did not acquire a business. This is because Big Pharma Co. only obtained the rights to access inputs through its license of pre-clinical intellectual property and did not employ or otherwise have access to Development Inc.'s scientists. Big Pharma Co. did not acquire processes that are capable of producing outputs given the intellectual property is so early-stage. These inputs require significant effort from scientists in order to develop processes that would be necessary to produce outputs.

Note—the analyses and conclusions in Examples 2 and 3 would likely not be any different if Big Pharma Co. acquired, rather than licensed, the intellectual property from Development Inc.

Questions

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), Pamela Yanakopulos (312.298.3798), or Jeff Crawford (312.298.3264).

Appendix A

The following table highlights some of the accounting differences between a business combination and an asset acquisition under U.S. GAAP. For further U.S. GAAP differences and for a comparison of a business combination and an asset acquisition under IFRS, please refer to PwC's *A Global Guide to Accounting for Business Combinations and Noncontrolling Interests.*

Difference	***Business Combination***	***Asset Acquisition***
Intangibles, including goodwill	Recognize intangibles at fair value if they meet the identifiable criteria. Recognize goodwill as a separate asset.	Recognize intangibles but do not recognize goodwill. Reallocate any excess consideration transferred over the fair value of the net assets acquired to the identifiable assets based on relative fair value.
IPR&D	Capitalize as an indefinite-lived intangible asset until project has been completed or abandoned. IPR&D is measured at fair value.	Expense at transaction closing date if there is no alternative future use.
Contingent consideration	Record at acquisition-date fair value and record subsequent changes in fair value through earnings if classified as a liability.	Generally, record when probable and reasonably estimable. Depending on the stage of development, recognize subsequent changes as a component of the cost of the asset or in earnings.
Acquired contingencies	If fair value is determinable, recognize and measure at fair value at acquisition date or during the measurement period. Otherwise, record when probable and reasonably estimable.	Record when probable and reasonably estimable.
Assembled workforce	Does not qualify as an identifiable intangible asset to be recognized separately from goodwill.	Recognize and measure as intangible asset if part of asset or group of assets acquired.
Deferred taxes	Record most temporary book/tax differences for assets acquired and liabilities assumed with an offsetting entry to goodwill.	Measure using the simultaneous equations method, to the extent temporary book/tax differences exist.
Transaction costs	Expense as incurred.	Record as a component of the consideration transferred to acquire the group of assets.