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Accounting Treatment Pitfalls to Avoid in Life Sciences M&A

As M&A activity in the life sciences industry continues to be strong, driven by big pharma divestitures of off-strategy drugs, buyers hoping to develop acquired products into profitable assets must use significant judgment in applying guidance on the accounting treatment of these M&A transactions. The critical issue that needs to be addressed is: might the acquisition be treated as a business combination under generally accepted accounting principles, or GAAP, but an asset acquisition by the U.S. Securities and Exchange Commission, and what are the consequences?

As we discuss below, the application of the guidance in Accounting Standards Codification 805-10-55, or ASC 805, for business combinations can differ significantly depending upon whether the acquired entity is considered a "business" or an "asset." Similarly, SEC Regulation S-X, Article 11-01(d), or SEC Rule 11-01(d), is the guidance used to determine whether a registrant acquired a business or an asset and consequently whether historical financial statements of the acquired business are required to be filed with the SEC. This article will discuss some of these critical accounting issues related to these acquisitions.

Generally speaking, the buyers in these life sciences transactions are either companies with the infrastructure in place to commercialize the acquired products, or private equity firms looking to drop acquired licenses and technology into newly formed companies with the ultimate goal of an initial public offering. But regardless of what the acquirer's plans are, the following two questions arise:

- How should the acquisition be accounted for in accordance with GAAP?
- Should the historical financial statements (prior to acquisition) of the acquiree be filed with the SEC?[1]

The answer to each depends on whether the acquisition is a business or an asset or group of assets. Since GAAP and the SEC each have their own unique framework to define what constitutes a business, it is possible to conclude that an acquisition is a business combination under one but an asset acquisition under the other.

GAAP

ASC 805 is the guidance to determine how an acquisition should be accounted for, either as a business combination or an asset acquisition. The Financial Accounting Standards Board changed the definition of a business in January 2017 in response to criticism that the former definition was overly broad and resulted in many transactions accounted for as business combinations that were more akin to asset acquisitions. The focus of the FASB definition is on the operations of the acquiree: ASC 805-10-55-4 states that 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."

Prior to assessing the inputs, processes and outputs, an initial screen test is performed which considers whether substantially all the fair value of the acquired assets is concentrated in a single asset or group of similar assets. An acquisition may include products in a number of different areas (e.g., geriatric, oncology, renal) and each in various stages of development (e.g., preclinical, clinical, commercial). This assessment requires significant judgment, particularly when grouping similar assets. When grouping, an entity should consider the nature of each specific asset and the associated risks with managing and creating outputs from each. If the acquirer concludes that substantially all the fair value of the acquired assets is concentrated in a single asset or group of similar assets, no further analysis is necessary, and the transaction is accounted for as an asset acquisition.

If the screen test does not result in an asset acquisition, the next step is to determine whether the acquisition includes inputs and a substantive process that either produces outputs or is capable of producing outputs. Since precommercial products do not include outputs (i.e., product revenue), more focus is placed on the acquired inputs and processes. The processes can be activities performed by the acquiree's employees or third-party providers, such as a contract research organization, a contract manufacturing organization or a combination of both. If the acquired entity has inputs and a substantive process or processes capable of producing outputs, the acquisition is accounted for as a business combination.

SEC

SEC Rule 11-01 (d) focuses on the "continuity" of the operations after the acquisition, to wit: "the term business should be evaluated in light of the facts and circumstances involved and whether there is sufficient continuity of the acquired entity's operations prior to and after the transaction so that disclosure of prior financial information is material to the understanding of future operations."

For precommercial life science transactions, particular attention is on the stage of development:

- Were there any pre-acquisition revenues (e.g., collaboration arrangements)?
- If so, will they continue in the same form?
- Is the product close to commercialization or are there substantial R&D efforts that will continue?

Other considerations include:

- Are any employees part of the transaction?
- Are physical facilities part of the transaction?
- Does the transaction include critical CRO and CMO arrangements in place that provide continuity of the operations?

If the registrant concludes that a business has been acquired, SEC Rule 3-05 determines the time period of the acquiree's financial statements that are required. Depending on the significance of the acquisition, up to three years of audited financial statements may be needed.

Summary

While the assessment of GAAP and the conclusion for the accounting of the acquisition is important, the need to address the SEC reporting requirements of the acquiree's historical financial statements in a timely manner cannot be overemphasized. Once the acquisition occurs, the clock starts ticking for a registrant to file the necessary financial statements and any delays could prevent planned share offerings or other transactions. The availability and access to the acquiree's information needed for audited financial statements, may be limited. In many life science acquisitions, the acquired business is not a separate legal entity nor does standalone financial information exist, and therefore carve-out financial statements will be needed. The preparation of carve-out financial statements typically entails a level of complexity, including ensuring that all assets, liabilities, revenues and costs associated with the acquired business are identified, as well as allocations to and from the parent are considered. In addition, all such financial information needs to be supported by sufficient documentation to meet the obligations of the auditors.

In any event, as soon as possible, the registrant should consider the need to create a dialogue with the SEC if they conclude that the acquisition will be treated as an asset acquisition for the SEC but a business combination for GAAP. Even if the registrant concludes the acquisition is a business combination for the SEC, the SEC may accept limited financial information (e.g., statement of direct expenses) of the acquired business in lieu of a full presentation of financial statements required by GAAP. Preclearance with the SEC prior to filing a registration statement or periodic financial statements could prevent unexpected delays or other complications.

[1] GAAP prescribes the accounting model to be followed for the acquisition by the acquirer while the SEC prescribes whether audited historical financial statements of the acquired entity need to be filed with the SEC and if so, what periods are required.

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