Maximizing the Value of the Orphan Drug Tax Credit

The Pharmaceutical and Life Sciences industry currently faces a range of issues, including the rising costs of discovery and development, major losses of revenue due to the patent expirations, and increased complexities due to demanding regulatory requirements. Moreover, developers of orphan drugs must overcome a host of additional challenges that make it difficult to recoup investments made to discover, develop, and deliver the new therapies.

As a result, orphan drug developers are being forced to do more with less and are constantly turning to available incentives as a means of increasing their return on investment. Two of the available incentives include the R&D Tax Credit and the Orphan Drug Tax Credit ("ODC").

Companies that have qualifying activities for the ODC may also qualify for the R&D Tax credit, but both credits cannot be claimed for the same expense. The ODC often provides a more lucrative benefit than the R&D Tax Credit. Yet, companies often fail to fully maximize the ODC that they are otherwise eligible to claim due to a lack of knowledge, expertise and/or resources.

In order to fully maximize an ODC claim, orphan drug developers should consider the following:

- **Annual Pharmaceutical Fee**: Orphan drugs are excluded from the annual excise tax imposed upon the sales volume of certain branded pharmaceuticals. However, the ***exclusion applies only if*** the taxpayer filed an actual claim for the ODC on its tax return. Furthermore, if the expenditures were claimed via the R&D Tax Credit as opposed to the ODC, the exclusion will not apply. Therefore, the consequences of not claiming the ODC can result in hefty fees when the drug is brought to market.

- **Foreign Activities**: Special provisions may allow eligible testing costs related to activities conducted outside the United States to qualify (as opposed to the full exclusion required for purposes of the R&D Tax Credit).

- **Vendor Costs**: An ODC claim should include one-hundred (100) percent of qualified vendor costs (as opposed to the sixty-five (65) percent allowance used for R&D Tax Credit purposes).

- **Base Period:** The rules require that the expenditures claimed for purposes of the ODC be added back to the R&D Tax Credit base amount for subsequent tax years. However, the impact of the add-back is mitigated by the requirement that only sixty-five (65) percent of the qualified vendor costs need to be included in the base amount (as opposed to the (100) percent claimed for ODC purposes).

- **Other:** There are circumstances that allow a taxpayer to claim both the ODC and the R&D Tax Credit for the development of the same orphan drug.

Given the significant tax savings offered by the ODC, it should be no surprise that these claims are often subject to increased scrutiny by the relevant taxing authorities. Therefore, it is critical that these claims are substantiated with the appropriate types and level of documentation.

Orphan drug developers may want to take a fresh look at their ODC claims to ensure that they are claiming the maximum available benefit as well as whether there is sufficient evidentiary documentation needed to substantiate the qualified nature of the credit.

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