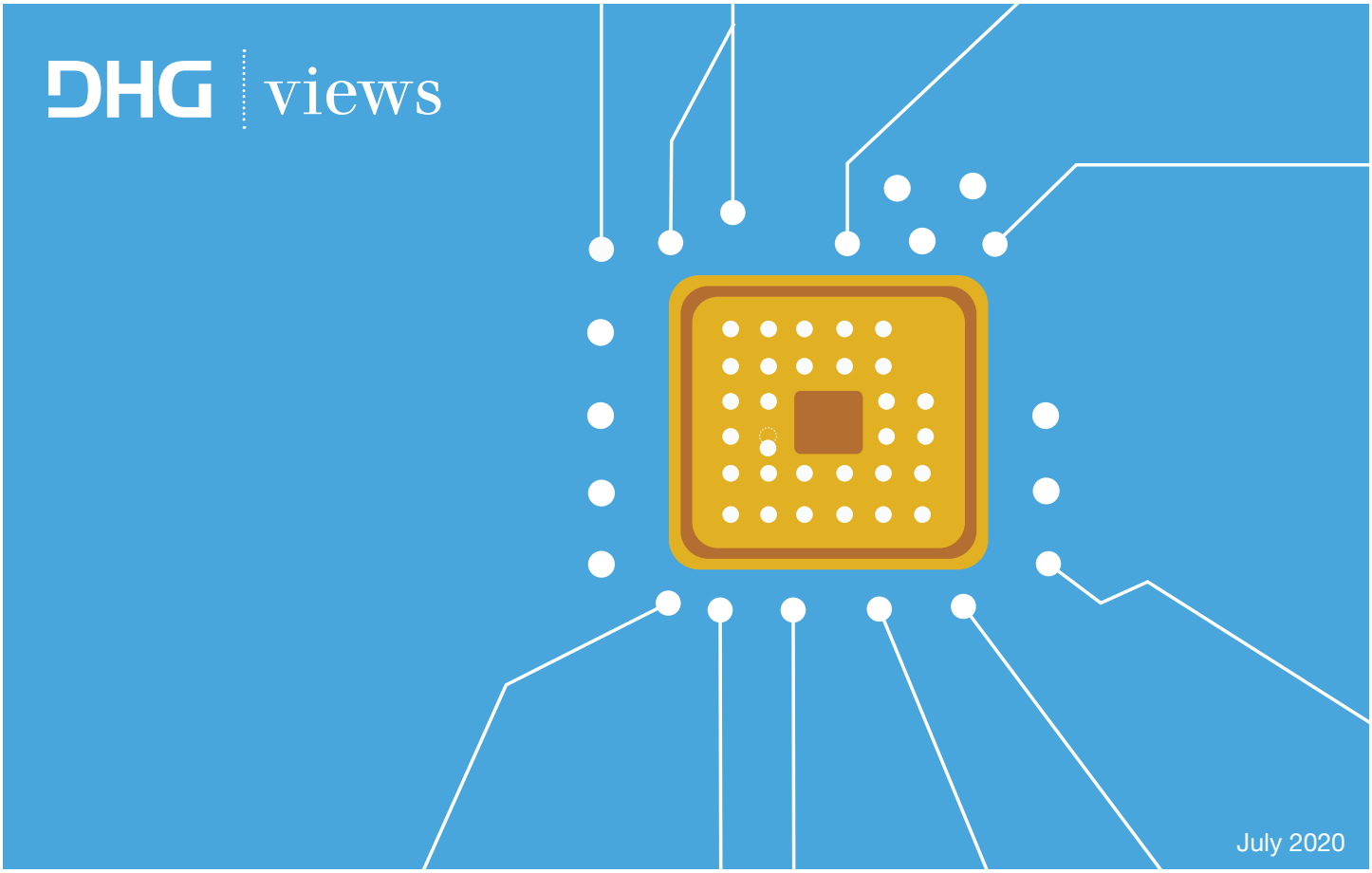
DHG views



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Weathering the Pandemic with R&D and Orphan Drug Tax Credits

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With the constant discussions surrounding how to weather the COVID-19 storm, more technology and life sciences companies should be evaluating their ability to take advantage of the Credit for Increasing Research Activities (R&D tax credit) to potentially realize substantial cash tax savings. In addition, many life sciences companies that are focused on developing products in accordance with the Orphan Drug designation may be able to take advantage of the Orphan Drug 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 generally provides a greater benefit compared to the R&D tax credit. DHG can help evaluate qualified costs to enhance utilization of either credit.

Although COVID-19 hasn't directly altered the R&D tax credit nor the ODC, there are examples of why now is an opportune time to pursue these credits:

- May result in immediate cash savings to improve liquidity.
- Technology and life sciences companies may have an increase in their employees' capacity to assist in pursuing these value-driving incentives.

What is the R&D Tax Credit?

Since the 1980s, the R&D tax credit has been claimed by many industries, including manufacturers, software developers, chemical companies, technology companies and pharmaceutical companies. The tax incentive comes in the form of a federal tax credit that offsets tax liability dollar-for-dollar. In addition to the federal credit, many states have R&D tax credits of their own. The combination of these incentives can potentially provide major savings for companies that qualify.

How can technology and life sciences companies qualify for the R&D tax credit?

The R&D tax credit is an incentive designed to encourage businesses to invest in developing new or improved

processes, techniques and products. Many companies in the technology and life sciences industries actively work on product development that incorporates new features or functionality with respect to biotechnology, pharmaceuticals, medical devices or other new technology.

Below are examples of activities that technology and life sciences companies often conduct that may qualify for the R&D tax credit:

- Design Activities:
  - » Clinical trial phase work (phase 1-3)
  - » Designing drug formulations to improve efficiency, yield, output, shelf life or reduction of side effects
  - » Pre-clinical/molecular design of new drug products
  - » Designing methodologies or procedures to comply with medical and regulatory affairs and Food and Drug Administration (FDA) requirements
  - » Exploring alternative designs to determine which ones best meet a customer's needs
  - » Exploring opportunities for cost savings
  - » Designing and manufacturing prototype devices, drug delivery systems or medical packaging applications
  - » Developing automated processes to implement new hardware/software
- Testing Activities:
  - » Exploring alternative materials or combination of materials in drug development to determine which formulas best meet customer specifications
  - » Testing conducted on initial production runs of clinical trial lots and initial scale-up of manufacturing processes
  - » Testing prototype devices for functionality and features
  - » Running simulations and models to evaluate success/failure of functions and features
  - » Exploring alternative means and methods/techniques of designing new drug products
  - » Supporting testing such as quality assurance and quality control to confirm and validate specifications on new drug products

The above list is not all inclusive. Many companies conduct various activities that may meet R&D qualification criteria.

Qualifying Activities Example

A medical device company is engaged to design and develop a new product for patients that involves technical uncertainties surrounding the design and structure. The company goes through an iterative process to design and develop a prototype that meets the functional requirements and conducts various testing procedures to confirm and validate functionality. In addition to meeting product specifications, the company must also evaluate how to design their product to meet various medical regulatory requirements involving interference with other medical devices, packaging, and other constraints.

What is the Orphan Drug Tax Credit?

The ODC is available to life sciences and pharmaceutical companies that are focused on developing new drugs to cure certain rare diseases. These diseases often impact small populations and are not typically high priority in terms of drug development by pharmaceutical companies. Like the R&D tax credit, the ODC provides a federal tax credit benefit and opportunity to increase cash flow and reduce the cost of their development operations.

In order to qualify for the ODC, companies must be working on specific drugs that have received the Orphan Drug designation by the FDA. The qualifications for this designation are:

- A disease that affects 200,000 people or less within the United States; or,
- A disease that affects over 200,000 people within the United States, but for which there is no expectation that the cost for developing such a drug will be recovered from the sale in the United States.

The qualification requirements for the ODC are similar to the R&D tax credit. Companies that conduct activities on the clinical phase of a drug's development will generally meet the same requirements above for the R&D tax credit (e.g., developing new or improved processes, techniques and products). These requirements are designed to address research activities that focus on solving technical uncertainty through iterative experimentation efforts. Both credits must be separately calculated and qualified costs cannot be claimed for both credits.

How Technology and Life Sciences Companies Can Pursue the R&D and Orphan Drug Tax Credits

DHG's process for pursuing the R&D tax credit and ODC (if applicable) involves the following phases:

1. Scoping (Cost / Benefit Analysis)

The first phase of evaluating a potential R&D tax credit is identifying if the company has qualified activities, and then estimating the cost associated with each activity. This analysis is typically performed by working with key employees who have visibility over the entire organization and its activities. This exercise provides information needed

to estimate the company's overall R&D tax credit benefit available for the current tax year, as well as prior tax years that can be amended. In addition to estimating the overall benefit, this step includes evaluating the information available to document the activities and estimating the cost of pursuing the benefit. If applicable, qualified activities and costs related to Orphan Drug development will also be evaluated for applicability of the ODC. This allows the company to minimize its investment in exploring the opportunity until the overall benefit and pursuit cost is determined.

2. Execution of the R&D tax credit study

Executing the R&D tax credit study involves capturing actual qualified costs for the various qualified activities, using the qualified costs to calculate the R&D tax credit, obtaining project-specific supporting documentation to prove qualification (design plan iterations, testing documentation, clinical trial reports, etc.) and interviewing subject matter experts or project managers to document the projects in order to demonstrate qualification. The results of this phase are the applicable R&D tax credit forms and a packaged deliverable designed to support the R&D tax credit claimed both quantitatively and qualitatively for Internal Revenue Service (IRS) and state audit purposes. DHG can provide applicable ODC tax forms and an audit-ready deliverable for companies that conduct development products meeting the Orphan Drug designation.

3. Filing tax returns / amending prior year returns

After the R&D tax credit study is completed, the tax returns can be filed or amended and will include the applicable federal and state R&D tax credit forms (and federal ODC, if applicable). Both the R&D tax credit and ODC can directly offset tax owed, and cash savings are often realized immediately with an originally filed return. If an amended return is filed, then the IRS will process the amended return and issue a refund of taxes previously paid, if applicable.

Potential IRS or State Audit

In the event that a company's R&D tax credit or ODC is audited by the IRS or a state taxing authority, the company will be notified by the respective taxing authority, and the taxing authority will request information that demonstrates the company's eligibility for the credit and the process used for calculating the company's R&D or Orphan Drug tax credit. The IRS requires extensive documentation to support an R&D tax credit or ODC claim. Having a thoroughly documented credit study is instrumental in navigating IRS and state audits.

An Opportunity for Start-Ups

For tax years beginning after Dec. 31, 2015, eligible small businesses (those with $50 million or less of gross receipts) may claim the R&D tax credit against AMT liability.

In addition, qualified start-up companies may elect to use up to $250,000 of the R&D credit against payroll taxes. Qualified start-ups must meet the following two requirements:

- Have fewer than $5 million of gross receipts for the credit year; and,
- Have no more than five years of gross receipts.

Conclusion

Technology and life sciences companies performing activities such as those highlighted above should certainly evaluate the R&D tax credit opportunity. It is crucial to utilize an acceptable methodology for computing and documenting an R&D tax credit claim that can withstand scrutiny under IRS examination. Capturing the cash savings is generally well worth the time and effort required in determining eligibility and pursuit of the R&D tax credit.

In addition, life sciences companies that are actively conducting R&D activities to find cures using drugs given Orphan Drug designation should evaluate their opportunity to claim these expenses using the ODC. The ODC savings generated are often even more lucrative than a traditional R&D tax credit.

For questions, contact your DHG advisor or technology@dhg.com.