R&D Tax Incentive Opportunities for Life Sciences Companies - A Point of View
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Executive Summary

Since 1981, taxpayers have been able to reduce the cost of R&D through the research and development tax credit.\(^1\) The credit is by no means a secret or new — considering that more than six billion dollars in R&D credits were claimed in 2005.\(^2\) The research credit is nonetheless widely misunderstood by many companies and their executive teams due to the ever changing landscape of interpretive rulings, regulations and documentation standards.

In an era where life sciences companies are rapidly witnessing industry consolidation, global expansion, off-shoring of manufacturing and clinical trials, and increased scrutiny of the R&D process, the research credit is more important than ever. This Point of View will touch broadly upon these issues, address various complexities with the calculation, and provide guidance for companies to consider when trying to effectively document and address the tax credit surrounding their R&D processes.

Additionally, it will address the:
- extension of the R&D tax credit through 2009,
- recently enacted Alternative Simplified Credit,
- additional aspects of the Housing and Economic Recovery Act of 2008 providing the option to claim a refundable research tax credit in lieu of bonus depreciation, and
- tax implications of the Orphan Drug Credit and potential issues associated with only considering orphan designation from a sales and marketing perspective.

\(^1\) Please note that this article focuses exclusively on US federal research credits under Internal Revenue Code §§ 41 and 174. While this article does not consider additional state-and-local and global tax incentives for engaging in research, this is not intended to convey the message that such benefits are trivial. For example, California has one of the largest research credits in the country and, unlike the federal research credit, is permanent.

General discussion of the R&D tax credit for Life Sciences companies

With respect to the many complexities in the calculation and documentation of the R&D tax credit, it is important to take a moment to discuss the fact that the Internal Revenue Service (IRS) has designated the research credit as a "Tier One" issue under its new Strategic Initiative. A Tier One issue is described by the IRS as: “an issue determined to have the greatest compliance risk and has an impact on more than one broad industry.” The Tier One designation has placed compliance issues on the forefront of considerations – particularly whether there is acceptable documentation to substantiate the credit.

Life sciences companies should consider whether they are capturing all potentially qualifying activities – which may be occurring outside of the traditional R&D cost centers. This is particularly important as many biotechnology and pharmaceutical companies shift their R&D investment strategy from one or two blockbuster drugs, to one of a larger and diversified portfolio of products in the pipeline. With each launch, there are associated manufacturing and R&D costs that may be eligible for tax credits.

Below are a few examples of industry initiatives that illustrate the breadth of activities that may qualify as eligible R&D tax incentives:

• Developing new or improved pharmaceuticals, biologics or medical devices
• Developing production processes for new products, including FDA qualification, validation, and clinical testing during Phases I-IV clinical trials
• Establishing a new factory or production line where new technology is employed or new manufacturing techniques are used
• Manufacturing experimental qualification lots and clinical trial lots
• Manufacturing process scale-up design and development efforts
• Creating cross-functional process improvement teams, including production and maintenance employee activities as well as continuous improvement initiatives
• Developing technology for compliance with EPA requirements and environmental remediation
• Developing new product and process assays
• Designing and developing certain hardware and software systems for use in research and clinical development, and medical device equipment used for treating various diseases
• Developing product improvements to increase the shelf life or stability of an existing product and reformulation to reduce side effects or dosage
• Supporting new or improved product development through pharmacovigilance data collection activities, biometrics analyses, informatics, quality, etc.
A current industry trend in life sciences is the movement of manufacturing facilities and clinical activities offshore. Companies are increasingly moving production facilities to an emerging market for lower production costs, or moving production to other jurisdictions for protection and leniency of intellectual property. Increasingly, life sciences companies are also conducting clinical trials outside the US either for cost benefits or for access to certain patient populations, such as countries with patients’ naïve to certain treatments. These activities have been occurring with greater frequency in recent years.

However, when moving manufacturing or clinical trials offshore, companies must realize that qualifying research and development activity must occur in the United States. For payments to outsourcing companies to be qualified, there are specific requirements that must be met.

The following table illustrates activities Pharma and Biotech companies are considering off-shoring.

Functions being considered for outsourcing by Pharma and Biotech

<table>
<thead>
<tr>
<th>Functions being considered</th>
<th>To a great extent</th>
<th>To some extent</th>
<th>Not at all</th>
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<td>Clinical trials</td>
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<td>Formulation</td>
<td>41</td>
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<td>21</td>
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<tr>
<td>Large scale mfg (small molecules)</td>
<td>47</td>
<td>24</td>
<td>15</td>
</tr>
<tr>
<td>Discovery</td>
<td>50</td>
<td>24</td>
<td>12</td>
</tr>
<tr>
<td>API</td>
<td>48</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Large scale mfg (bio)</td>
<td>58</td>
<td>12</td>
<td>8</td>
</tr>
</tbody>
</table>


There are two principal areas to consider with respect to global expansion.

1. Manufacturing – Increasingly, life sciences companies are contracting globally or off-shoring manufacturing activities. The costs incurred to develop manufacturing IP in the US may potentially qualify, but may also require that companies examine the purchase of materials used in the research effort to segregate out the expense. While all qualifying R&D labor must occur in the US, materials used in research can be purchased ex-US. If a company can segregate the cost of the purchase of materials, the cost can be included as Research and Development if the materials are primarily used in the R&D process. Examples include: (i) the purchase of Active Pharmaceutical Ingredient (API) which is then utilized in the US for further testing, (ii) the purchase of the drug product that is produced outside the US but intended for use in US clinical trials, or (iii) supplies for use in development of a new or improved manufacturing or development process in the United States.
2. Clinical Trials — Clinical Trials are being conducted with increasing frequency outside the United States. Life Sciences companies need to make certain that data from clinical trials is made available by the Contract Research Organization (CRO) running the global trial on behalf of the company to enable costs to be segregated between US and ex-US activities. Generally this data is available if the US company has worked with the CRO to make certain that appropriate data points are captured. If Life Sciences companies do not take these measures in advance with their CRO, it becomes a complicated and challenging look-back process to determine what costs will potentially qualify. To provide the necessary accounting when contracting with a CRO or conducting other means of global trials, it is of critical importance that these discussions occur in advance.

With respect to global expansion and clinical trials, there are two notable and favorable exceptions to consider. First, the R&D activities that are conducted in the US as part of overall global trials will potentially qualify as research expenditures under the US rules. Second, with respect to clinical trials pertaining to an Orphan Drug, R&D activities will potentially qualify even if they occurred outside the US, if it is deemed necessary because a US patient population is not large enough to sustain trials within the United States. The Orphan Drug exception will be addressed later in this document.

Offshore testing

Since 1997, scientists based outside the United States have represented a growing portion of the medical researchers who register with the Food and Drug Administration to conduct human studies of drugs.

Offshore testing on the rise:

Source: Tufts Center for the study of drug development
Refundable research tax credit available for 2008 and 2009

Generally, the R&D credit is a non-refundable tax credit, i.e., companies can utilize the credit to reduce their current tax liability, reduce their estimated tax payments for the current year, or carry back the credit one year to generate a refund for income taxes paid in the prior year. Congress recognized, however, that early-stage biotechnology, pharmaceutical, and medical device companies have not been able to utilize the credit because they are not in a taxable position. The Housing and Economic Recovery Act of 2008, signed into law on July 30, 2008, provides a limited exception to this rule, thereby providing an opportunity for cash refunds for companies who cannot otherwise utilize their research credits. This special tax benefit, under section 168(k)(4), allows corporations to claim refundable tax credits in lieu of 50-percent bonus depreciation for certain capital investments made during the period of April 1, 2008 through December 31, 2009. The maximum benefit is $30M and only 6% of their carryforward credits from prior to 2006 can be cashed in. The “price” companies’ pay for this benefit is giving up accelerated bonus depreciation. Companies interested in this benefit must move quickly because there are strictly enforced rules regarding the timing of the election that must be made to take advantage of this opportunity. i.e., elections must be made on timely filed original returns in most cases. Moreover, the calculation of this benefit is complicated and beyond the scope of this article.

The enactment of the provision has been favorable to taxpayers on both the financial and policy fronts. First, it serves to provide a cash infusion for companies at a time when there is a severe capital crunch in the financial markets. For example, emerging biotechnology companies that made new capital investments during much of 2008 in qualifying laboratory equipment, software, or those gearing up for commercialization, will be able to receive a refundable tax credit (i.e., the amount of the credit will be refunded to the company, even if it is not paying taxes as it is in a “loss” position). Second, the enactment of this provision is an important policy victory for this industry in that it reflects Congress’ growing understanding that many Life Sciences companies, while not yet profitable, are engaged in research that is highly valuable to the growth and well being of our nation.

Since the tax code generally requires a company to use its accumulated Net Operating Losses (NOLs) before its tax credits can be claimed, the ability to use R&D credits is doubly beneficial in the life sciences industry. As a result, R&D credits may expire before they can be fully utilized. The provision not only allows companies to accelerate the date when they can claim their R&D credits, it also allows companies to claim credits that might otherwise expire and be permanently lost to the taxpayer.3

Here is an example of an early stage biotechnology company that took advantage of this new law: The company had accumulated nearly $30 million of unused R&D credits from 2005 and earlier years that they had been carrying forward since they had not generated taxable income. The company opened a new facility to manufacture clinical trial supplies in 2008, which would have afforded them bonus depreciation. Their carryforward credits could not be utilized in 2008 due to their loss position, and bonus depreciation merely increased their losses, providing no immediate tax relief. This company was nonetheless able to make a timely election to monetize a portion of their carryforward R&D credits in 2008 in lieu of bonus depreciation allowance. This election provided the company a nearly $2 million cash refund by enabling them to cash-in research credits that could not be utilized in 2008 – and may have never been utilized due to the limited period for carrying forward research credits.

3 R&D credits post-1998 may be carried forward for 20 years. Those before 1998 expire after 15 years.
An Orphan Drug is a classification of drug that has been specifically developed to treat a unique or rare medical condition, and is marked by a small class of patients that suffer from a particular disease or ailment. The government enacted the Orphan Drug Act of 1983 to incentivize biotechnology and pharmaceutical companies to work to combat these unique conditions rather than purely focusing on developing larger more widely applicable (and therefore more profitable) drugs. Often overlooked, the ‘Orphan Drug’ designation is more than just a pharmaceutical marketing position. It provides a significant tax benefit, as well. Although Orphan diseases affect a much smaller class of patients, the US government is incentivizing large companies to develop specific drugs to help the limited patient classes through various incentives including the Orphan Drug Credit (ODC).

The ODC provides a very lucrative incentive in the form of a significant tax credit available for certain activities related to developing the orphan drug. From a technical standpoint, we are providing a brief description of activities that may qualify under the ODC regime.

Section 45C(a) of the Internal Revenue Code (IRC) provides that taxpayers may claim a credit against income tax equal to 50% of “qualified clinical testing expenses” paid or incurred during the taxable year. IRC Section 45C(b) defines the term “qualified clinical testing expenses” by reference to section 41(b) – which defines expenses qualifying for the section 41 research credit – except that section 45C expenses must be incurred with respect to “clinical testing” (as defined below) of an orphan drug or biological product, rather than simply being incurred with respect to the broader category of “qualified research” described in section 41(d). As a consequence of this cross-reference to section 41(b), the following expenses incurred with respect to clinical testing of a designated orphan drug are eligible for the section 45C credit:

1. “in-house research expenses,” meaning (a) wages paid to employees for directly engaging in, or directly supporting or supervising, clinical testing of an orphan drug, (b) amounts paid for supplies used in the conduct of such clinical testing, and (c) certain amounts paid to another for the right to use computers in the conduct of such clinical testing; and
2. “contract research expenses,” meaning amounts paid to any person (other than an employee) for clinical testing of an orphan drug undertaken on the payor’s behalf.

An important element of the ODC focuses on availability to include as qualified expenses those expenses related to activities which occurred outside of the US. As Orphan diseases are rare and therefore patients may be scarce, the required testing patient population in the United States...
may be difficult to obtain. Thus, many companies are finding patient pools on a global scale. As globalization of clinical trials increases, the ODC allows a company to potentially deduct a significant portion of its related expenses that would not have otherwise been available to offset costs of globalized clinical trials. If a company can demonstrate that there are not a sufficient number of patients with the particular condition, disease or ailment in the United States to allow for efficient enrolment of a patient class such that conducting the clinical trials solely in the U.S. would lead to a delay of several years in obtaining the required testing results, it is likely that the exception for foreign testing under section 45C(d)(2)(A) would be available.

If a company does not receive Orphan designation before clinical trials begin, then the credit may be lost for certain tax years. This incentive is available once a company receives orphan designation and up until the date of FDA approval for that drug (for any indication). Consequently, it is essential that a company who is applying for Orphan status do so very early in the research process to take advantage of the credit in early years of the development effort. This valuable tax benefit should dispel the common misunderstanding that the Orphan Drug Act is only important for product marketing purposes.
Alternative Simplified Credit and the benefits to election

Current IRS enforcement policies have forced tax departments and R&D functions to focus on whether they have the documentation needed to determine, as well as to sustain, R&D tax credits. This is due, in part, to the fact that the research credit is an incremental credit computed on the increase of research spending over the amount the company would be expected to spend on research (called the “base amount”). Determining the base amount for the traditional credit requires companies to substantiate the amount of research spending during the years from 1984 – 1988, or for the initial years of operation (if not in existence during 1984-88). The IRS’s Tier One program directs IRS examiners to focus on whether research credits are adequately substantiated – not only for the current year – but also for the base period. What makes this issue particularly difficult to address is that there is no clear legal standard defining “adequate substantiation.” Recognizing the difficulties taxpayers faced in substantiating research spending occurring 10 – 20 years ago, led to the enactment of the Alternative Simplified Credit (ASC) – which eliminates the need to substantiate research spending occurring many years ago. This new credit option is particularly beneficial for life sciences companies, which often lack the time and resources to effectively document the R&D process in real-time and, thus, may not have the records often requested by IRS examiners to substantiate the traditional base amount.

The ASC provides companies the opportunity to claim a credit without having to compute the historical base amount by simply quantifying their qualified R&D expenditures for the current tax year and the previous three tax years. The base amount is 50% of the average prior three years of qualifying R&D expenditures. Taxpayers then get a credit equal to 12% (7.8% after the Section 280C(c) reduced credit adjustment) of the excess R&D spend over this base amount. This credit amount increases to 14% (net 9.1%) for tax years ending in 2009. So unless a taxpayer’s R&D spend is down significantly, they would virtually be assured of getting a credit under the ASC, but may not be able to get over the traditional base amount.

The opportunity is also significant for taxpayers who historically have not claimed a credit and have a fiscal year ended in 2009 because they can claim the 14% ASC credit for the entire year, which ends in 2009. Fiscal year taxpayers can also take financial statement benefit for the ASC beginning in the quarter ending after December 31, 2006 (the first quarter following the effective date of the new law creating the ASC). Also, it is very relevant to taxpayers who had significant increases in revenue in recent years which resulted in a substantially increased base amount for the traditional credit.

It is important to note that the ASC is an elective credit and must be elected on a timely filed tax return. Once the ASC is elected for the tax year it is irrevocable, but only for that tax year, i.e., a taxpayer could not elect the ASC and then file an amended return reporting the regular credit for the same tax year. The ASC election does not, however, bind the taxpayer to that election for subsequent tax years because the regulations allow taxpayers to revoke the election by simply reporting the traditional credit on a timely filed original return. Consequently, taxpayers can elect in-and-out of the traditional and ASC credits as long as they are reported on timely filed original tax returns.

A few notable items:
Examples of companies that will benefit from the ASC would include companies which:
• currently are using the Alternative Incremental Credit or those who have no R&D credit due to base amount considerations;
• currently have limited credit opportunity due to increasing gross receipts;
• are planning a large research effort in the current tax year (relative to research spending in prior years);
• have difficulty determining their “regular” base amount due to lack of substantiation from the historical period; or
• are smaller companies that cannot justify the compliance cost of reconstructing data from the historical base period.
Conclusion

There are significant tax opportunities available for R&D activities being engaged in at Life Sciences companies. However, there have been changes to historical incentives and new incentives are available that make these tax opportunities significantly easier to claim, as well as potentially more lucrative. Now more than ever, companies are taking a new look at the opportunities available to save valuable tax dollars and to potentially infuse cash into their companies for the current year. Deloitte Tax is well-positioned to team with and help your company with compliance and strategic issues.

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