Abstract: Due to recently enacted legislation, startup pharmaceutical companies with orphan drug designation(s) are for the first time, facing a new, rare decision; to claim qualifying expenses under the Federal orphan drug tax credit, resulting in a larger, but generally delayed utilization of the credit (until sufficient tax liability exists to apply the credit against, up to 20 years) OR to claim qualifying expenses under the Federal research tax credit, in order to make an election allowing the research tax credit to be applied against payroll tax liability, resulting in a smaller, but more immediate benefit.

What’s New...

The December 18, 2015 enactment of the Protecting Americans from Tax Hikes Act of 2015 (“Path Act”)\(^1\), brought about, not only the long-anticipated, permanent extension of the federal research tax credit, but also created great benefits for the startup community. More specifically, for taxable years beginning after December 31, 2015:

- eligible small businesses\(^2\) with average annual gross receipts for the 3 taxable years preceding the year of credit of less than $50 million may apply the research tax credit against alternative minimum tax (“AMT”); and

- certain startup’s that meet the criteria of a qualified small business may elect to apply the research tax credit against their payroll tax liability, up to a maximum amount of $250,000. Criteria for a qualified small business includes gross receipt of less than $5 million for the taxable year in which the credit is being claimed, and not having any gross receipts PRIOR TO any taxable year preceding the 5-taxable-year period ending with the taxable year in which the credit is being claimed.

What’s Old…but still great

Enacted in 1983, the federal orphan drug tax credit was created to facilitate the development of orphan drugs. Meaning, drugs to treat an indication (a disease or condition) which, as designated by the FDA, is so rare or uncommon that it effects less than 200,000 people in the U.S. The orphan drug credit benefit is equal to 50% of qualifying clinical testing expenses, which is a much greater benefit percentage than offered under the research tax credit, which generally, equates to approximately 6-13%\(^3\) of actual percentage varies based upon many factors including, but not limited to, credit calculation methodology elected (i.e. traditional versus Alternative Simplified Credit), base period amounts, etc.

\(^1\) This Act was included as part of the larger, legislative package entitled, Consolidated Appropriations Act, 2016 (Pub. Law 114-113).

\(^2\) Entity must be a non-publicly traded corporation, partnership, or sole proprietorship.

\(^3\) Actual percentage varies based upon many factors including, but not limited to, credit calculation methodology elected (i.e. traditional versus Alternative Simplified Credit), base period amounts, etc.
qualifying research expenses (“QRE”), but also requires the calculation of an often complex base amount.

**What expenses do I claim under which credit?**

While the criteria for the orphan drug and research tax credits are largely the same, the credit amount and certain other attributes are not.

<table>
<thead>
<tr>
<th>Tax Credit</th>
<th>Research</th>
<th>Orphan Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualifying Criteria</td>
<td>4 part test</td>
<td>4 part test, plus must receive FDA orphan designation</td>
</tr>
<tr>
<td>Applicable Expenses</td>
<td>Qualifying Research Expenses (&quot;QRE&quot;)</td>
<td>Qualifying Clinical Testing Expenses (&quot;QCTE&quot;)</td>
</tr>
<tr>
<td>Credit Amount</td>
<td>6-13% of QRE</td>
<td>50% of QCTE</td>
</tr>
<tr>
<td>I.R.C. § 280C(c)(3) (reduced credit) election available</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Payroll Tax Offset Election Available</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Carryforward/Carryback Ability</td>
<td>Carryforward 20 years; Carryback 1 year</td>
<td></td>
</tr>
</tbody>
</table>

Under Internal Revenue Code (I.R.C.) § 45C⁴, orphan drug QCTEs are defined by cross-reference to the § 41 definition of QREs, but with the added requirement that expenses must relate to activities involving human clinical testing⁵. Thus, by definition, any expense meeting the criteria for QCTE has also met the qualifications to be claimed as QRE. However, any of such qualifying expenses may only be claimed under either the orphan drug credit OR the research tax credit, but not both⁶.

Generally, the orphan drug credit offers a much higher percentage of credit for each dollar of qualifying expense. Accordingly, often it may make sense to claim expenses that qualify under both programs under the orphan drug credit program, rather than the research tax credit. While there is a requirement under I.R.C. § 280C(b), to reduce otherwise deductible research expenses by the amount of the orphan drug credit, even despite this addback to taxable income, the benefit of the orphan drug credit is still generally the more lucrative option.

Contrasting this to the research tax credit, the percentage credit per qualifying dollar is much lower, and while there is also a requirement to add back the credit to taxable income, there is an election that can be made to circumvent the add back. An I.R.C. § 280C(c)(3) election⁷ is available, which allows for a reduced research tax credit to be claimed, in lieu of adding back the credit to taxable income. Therefore, even despite the I.R.C. § 280C(c)(3) election available under the research credit, the orphan drug credit still generally provides a greater credit percentage per qualifying dollar than the research credit.

Often, a pharmaceutical entity may be working on both human clinical trials for orphan designated drugs, while also performing other, non-orphan drug related activities (i.e. for the development of other drugs, compounds, treatments, etc.). Further, that same entity, may also be performing activities in regard to the development of new (or improvements to existing) manufacturing processes to produce both orphan and non-orphan drugs on a commercial scale. In these cases, the orphan drug and the research credit can be claimed in the same tax year, however expenses must be bifurcated and claimed separately, under each of the respective tax credit programs, without any expense being claimed under both. While noting that qualifying research credit activity includes both product and process development, the orphan drug credit qualifying activity must only relate to human clinical trials. Accordingly, if an orphan designated drug receives FDA approval for marketing exclusively, this would indicate that human clinical trial activity and thusly orphan drug credit qualification activity has ended. However, this may begin potential eligibility for development of manufacturing processes for that former orphan drug, to be claimed under the research tax credit.

For entities claiming both credits, there may be some opportunity areas that are often overlooked. A few examples include:

- **Foreign clinical testing expenses**⁸ - for orphan drug credit purposes only, clinical testing expenses outside the U.S. may be claimed, if such testing is required due to an insufficient patient population in the U.S.;

- **“Substantially All” Rule**⁹ for wages – closely examining each employee’s time for time spent on orphan drug versus non-orphan drug activity, while also in combination with the above mentioned foreign clinical testing activity, can help to identify employees who may have met the 80% or more threshold with orphan drug activity alone. Thus, creating the ability to

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⁴ Unless otherwise stated, all references to the "I.R.C." or "Section" are to the Internal Revenue Code of 1986, as amended, and all references to the "Regulations" or to "Treas. Reg." are to the Treasury Regulations promulgated thereunder.

⁵ See I.R.C. § 45C(b)(2).

⁶ See I.R.C. § 45C(c)(1).

⁷ May only be made on timely filed tax returns (inclusive of extension).

⁸ See I.R.C. § 45C(d)(2).

⁹ See Treas. Reg. § 1.41-2(d)(2)
claim 100% of their time under the orphan drug credit, while forgoing any percentage that may have otherwise been claimed under the research credit.

- **Required addback of QCTE to base amount of research credit**\(^{10}\) - commonly, the amount of QCTE is overstated when making the required add back to the research tax credit base amount, thus resulting in an understated research credit amount.

In short, the ability to identify these opportunity areas is critical to your benefit under both tax credit programs and often enlisting the assistance of an outside provider, specialized in Orphan Drug/Research tax credit claims, can be helpful in accomplishing your credit maximization objectives.

**How Does the New Payroll Tax Offset Apply to all of this?**

The payroll tax liability offset election is applicable to the research credit only, and is only available for tax years beginning after December 31, 2015. Furthermore, only up to $250,000 of research credit may be applied to offset payroll tax liability. In terms of timing, the credit gets applied to your payroll tax liability beginning the first quarter after which you have filed your tax return on which you have made the election (claimed the research credit), and gets carried forward to the continuous quarters until $250,000 in payroll tax has been offset. For example, the earliest a calendar year end tax filer would be able to make the election for the payroll tax offset would be for its tax year ending December 31, 2016. Assuming that return is filed in the 1st quarter of 2017, the research credit would be applied to offset 2nd quarter 2017 payroll tax liability.

Assuming the requisite criteria are met, the ability to elect to utilize the research credit to offset its payroll tax liability seems like it may provide a more appealing, immediate benefit. However, at what cost? For orphan drug eligible expenses, perhaps the resulting cost of forgoing the opportunity to claim those expense under that higher benefit, Orphan Drug Credit program, but for which you may not realize the benefit until sometime in the not-so-immediate future. Startup pharma’s with eligible orphan drug expenses are, for the first time, facing this age-old question in choosing options for claiming tax credits; which is better, less now, or more later?

For more mature companies with large amounts of taxable income, claiming the orphan drug credit may be the clear option, as they have the benefit of both worlds, the larger credit amount and immediate ability to utilize. But, for others, mainly fledgling startups, it can require quite a bit more discussion.

**Which is more beneficial…the larger, orphan drug credit to be utilized later, OR the smaller, but more immediate Payroll tax offset?**

It all depends. On what? Primarily, your current tax position, difference between the two credit amounts, cost of capital, etc. For entities that meet the criteria for both the orphan drug credit and the payroll tax offset for the research credit, there are many factors to be evaluated in regard to this decision, including, but not limited to: 

**Anticipated time frame of when you will be in a taxable position to be able to utilize credit carryforwards**

Considering the election for the payroll tax offset can only be made for tax years beginning after December 31, 2015, and the actual offset to payroll tax liability would not occur until the quarter following the filing of that tax return, the earliest a benefit would be received from the offset of payroll tax liability would be the 2nd quarter of 2017. The offset would be up to a maximum amount of $250,000, assuming that your research credit equaled or exceeded that amount. The offset would be applied to offset payroll tax liability in each subsequent quarter until a maximum of $250,000 in credit had been used.

Accordingly, if it is anticipated that the entity will be in a taxable position in the near future, say 2016 and/or 2017, in which case it can readily make use of tax credits, perhaps it may be beneficial to forgo claiming expenses under the research tax credit, as the wait for the larger orphan drug credit, would outweigh making a payroll tax liability election. However, for a new, startup pharmaceutical company in the pre-discovery or pre-clinical phase of development, which may have quite a

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\(^{10}\) See I.R.C. § 45C(c)(2).
time to wait to attain FDA approval, the anticipated date of being in a taxable position to be able to utilize an orphan drug credit may be in the much more distant future. In these cases, perhaps the more immediate, payroll offset may be a better option, but this would of course mean, claiming expenses under the research credit, yielding less per qualifying dollar than if the same expenses if claimed under the orphan drug credit.

**Difference between your Research Tax Credit and your Orphan Drug Credit amounts**

As previously mentioned, the same amount of qualifying expenses will result in different credit amounts under each credit program due to the different mechanics of the credit calculations. It is important to calculate or utilize a tax credit service provider to assist with the calculation of both. Only then will you know whether the difference between the two amounts is something worth waiting for. But how much is worth waiting for? And how long is it worth it to wait? These are very much entity-specific decisions driven by many factors, including analysis of company financials, internal rate of return, investment strategies, etc.

**Time Value of Money**

What is worth more…a dollar today or a dollar tomorrow? Some may say, well it’s all dependent upon what you would do with the dollar you received today. In applying this concept to $250,000 received today, it’s important to determine what your current cost of capital or rate of return is, in order to determine the point at which it makes sense to choose the orphan drug credit over the research credit payroll offset election (or vice versa). For illustrative purposes, please see the following example which shows the difference between both credits using the same qualifying expenses. For purposes of this example a $250,000 research tax credit was used, as only the first $250,000 of research credit is eligible to be applied to offset payroll tax liability. QRE amounts were estimated based upon such credit amount, however, actual QRE amounts can vary, based upon base period calculation methodology. Under the assumptions of this example, the future value of the $250,000 invested at a rate of X%, would take Y number of years to equate to the amount you would receive from the orphan drug credit. Another way of looking at this is, depending upon your rate of return %, if you would not utilize the orphan drug credit within Y number of years, then, at that point, the orphan drug credit’s value would be less than the research tax credit’s more immediate payroll offset, due to the time value of money.

<table>
<thead>
<tr>
<th>Wages</th>
<th>R&amp;D Credit</th>
<th>Orphan Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wages</td>
<td>1,000,000</td>
<td>1,000,000</td>
</tr>
<tr>
<td>Supplies</td>
<td>850,000</td>
<td>850,000</td>
</tr>
<tr>
<td>Contract Research</td>
<td>650,000</td>
<td>1,000,000</td>
</tr>
<tr>
<td>QRE or QCTE, respectively</td>
<td>2,500,000</td>
<td>2,850,000</td>
</tr>
<tr>
<td>Federal Tax Credit</td>
<td>250,000</td>
<td>1,425,000</td>
</tr>
<tr>
<td>Tax Effected benefit</td>
<td>250,000</td>
<td>926,250</td>
</tr>
</tbody>
</table>

At a rate of return of: | # of years it would take
- <10%                  | >13.7
- 10%                   | 13.7
- 20%                   | 7.2
- 30%                   | 5.0
- 40%                   | 3.9
- >40%                  | < 3.9

**IRS audit posture**

Whether claiming the research credit, orphan drug credit, or both, conducting a thorough study to appropriately identify, qualify, and quantify expenses is critical to sustaining such credit under IRS examination. Of equal importance is ensuring sufficient contemporaneous documentation is retained and readily available to support QRE and/or QCTE. While there is no guarantee of IRS audit, a high likelihood should generally be assumed.

Perhaps, in a few years, once there has been more history accumulated, the IRS’ review procedures in regard to research claims for which a payroll tax offset election has been claimed, whether more or less favorable, may be an added factor in deciding between the smaller, but more immediate payroll tax offset election or the larger, (but often later) ability to use the orphan drug credit.

**Key takeaway:**

While there may have always been the decision to claim expenses under the orphan drug or research tax credit programs, there is now the added wrinkle of determining whether to choose the research credit in order to make the payroll liability offset election. No matter whether you may qualify under either the orphan drug and/or research credit programs, and even if you’re uncertain as to when you will be able to utilize the credit(s), the time to capture, document, and claim the credit is now, while you are incurring such expenses.
About the author:
Kathleen Milone is a licensed CPA in both NY and DC. She currently is a Director in NYC at Tax Credit Co., one of the largest independent tax credit practices in the country. Previously, she was in the credits practice of one of the “Big 4” largest international professional services tax, consulting and auditing firms for over 10 years.