
Qualifying Therapeutic Discovery Project Tax Credit – IRS Guidance Issued on May 21, 2010

2010-05-24

The Treasury Department released IRS Notice 2010-45 (the "Notice") on May 21, 2010, which establishes the application process for the 50% investment tax credit on qualifying therapeutic discovery projects (the "Program") that was established by the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act").

The Notice provides the procedures to obtain certification by the Internal Revenue Service ("IRS") that a taxpayer's qualified investments for qualifying therapeutic discovery projects ("qualifying projects") are eligible for the 50% tax credit, or the alternative non-taxable grant (which permits companies that do not expect current federal income tax liability to still take advantage of the Program).

The Program is not allocating credits/grants on a first come-first served basis and there are limits on the amount available for each taxpayer. Accordingly, all companies with qualified investments for a qualifying project or projects (as determined under the rules) will receive some of the available credits if they timely submit their applications.

Applications for certification must be submitted to the IRS by July 21, 2010.

Requirements and Criteria

The Program is limited to qualified investments made in taxable years beginning in 2009 and 2010. The total combined amount available for credits or grants is \$1 billion, **with a cap of \$5 million of credits or grants in the aggregate for 2009 and 2010 for each taxpayer**, regardless of the number of projects the taxpayer may have.

The credit is only available to companies that employ 250 or fewer employees (with aggregation rules applying to affiliated companies or those under common control). The Notice clarifies that both full-time and part-time employees are counted as employees, but not leased employees.

Qualifying projects are those projects that are designed (as determined by the Department of Health and Human Services ("HHS")):

- to treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, clinical studies, and research protocols for the purpose of securing approval for a drug or biologic;
- to diagnose diseases or conditions or to determine related molecular factors by developing molecular diagnostics to guide therapeutic decisions; or
- to develop a product, process or technology to further the delivery or administration of therapeutics.

The Program will only consider those qualifying projects that show reasonable potential (as determined by HHS):

- to result in new therapies to treat areas of unmet medical need or to prevent, detect, or treat chronic or acute diseases and conditions;
- to reduce long-term U.S. health care costs; or
- to significantly advance the goal of curing cancer within the next 30 years (collectively, the "HHS Factors").

Additionally, the Program will take into consideration those qualifying projects with the greatest potential (as determined by the IRS):

- to create and sustain high quality, high paying jobs in the United States; and
- to advance U.S. competitiveness in the fields of life, biological, and medical sciences (collectively, the "IRS Factors").

Qualified investments that are eligible for the credit include costs paid or incurred for expenses necessary for and directly related to the conduct of qualifying projects, but excluding the following items:

- compensation for the CEO and the three highest-paid executive officers (other than the CFO, although the CFO's compensation may be an excluded indirect cost);
- interest expenses;
- facility maintenance expenses (such as mortgage or rent payments, insurance, utility or maintenance costs);
- indirect costs (such as general and administrative costs) related to administrative, service, or support departments (such as personnel, accounting, data processing, security, legal, etc.); and
- other expenses identified by the Secretary of the Treasury. The Notice clarifies that the Secretary has determined that the amount of qualified investments must be reduced by the amount of any grant the applicant has received that is excluded from gross income, unless the grant can only be used for costs other than qualified investment costs.

Expenses that are certified by the IRS as eligible for the 50% tax credit will not be deductible for tax purposes and cannot be used to generate research credits, orphan drug credits, or bonus depreciation. Additionally, the basis of any certified costs that are required to be capitalized and depreciated must be reduced by the amount of the credit related to those costs.

The maximum amount of qualified investments that will be certified by the IRS is \$2 billion (which would result in \$1 billion of credits or grants). The \$2 billion will be divided equally among each project that meets the criteria, but in no case will the amount certified for a qualifying project exceed the amount of the qualified investment for the project stated on the application. If the amount allocated to a project exceeds the qualified investment of the project, then the excess will be allocated to those projects that received allocations less than their applied-for qualified investments, until the full \$2 billion is allocated. In no event will a taxpayer receive certification for more than \$10 million of qualified investments for all of its projects for taxable years beginning in 2009 and 2010, resulting in a credit or grant of no more than \$5 million per taxpayer. If a taxpayer is allocated more than \$10 million of qualified investments for all of its projects, the excess will be allocated to qualifying projects that received allocations less than their qualified investments, until either the full \$2 billion has been allocated or each project cap or each taxpayer cap has been reached.

Applications

Complete applications for the primary allocation round must be submitted no earlier than the date on which the application form will be released (which is on or before June 21, 2010), and no later than July 21, 2010.

There may only be one round of certifications if the \$1 billion credit/grant limit is reached in this primary allocation round. Each application will be subject to a preliminary review to determine whether the applicant is an eligible taxpayer and whether the application is otherwise complete. Preliminary review of timely-filed applications will end on September 30, 2010. The IRS and HHS will begin a formal 30-day review process for all applications on October 1, 2010 and all determinations will be made no later than October 29, 2010.

A separate application must be submitted for each project for which a company seeks certification, but a single application may be made for qualified investments for that project for taxable years beginning in 2009, 2010, or both. The application is made up of two main parts: (i) Form 8942 -- Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program -- which is not yet available but will be released by June 21, 2010, and (ii) a Project Information Memorandum.

Form 8942 asks for the applicant's general information as well as information regarding the project and the applicant's employees and contractors working on the project in order for the IRS to evaluate the IRS Factors.

The Project Information Memorandum asks for project information that HHS will use to evaluate whether the project is a "qualifying therapeutic discovery project" as well as the HHS Factors.

Appendix A of the Notice provides details concerning the information that must be included on the submitted Form 8942 and the Project Information Memorandum. In addition, it sets forth strict rules regarding what may not be included (for example, extraneous information such as brochures and presentations may not be included), and the Project Information Memorandum has additional rules regarding formatting, and word limits for answering the questions posed.

We urge each company that intends to submit an application to review Appendix A of the Notice as soon as possible so that it can begin the process of drafting its Project Information Memorandum and gathering the data for the Form 8942.

Grants in Lieu of the Credit

An applicant must elect on its application form to take the tax credit as a non-taxable grant, and the application must still be filed on or before July 21, 2010. Nevertheless, if the election for a grant was not made on the application when it was initially filed, an applicant may amend its application after the July 21, 2010 application deadline to elect to receive the credit as a grant, but the election must be made no later than the due date (including extensions) for filing the tax return for the applicable taxable year.

Additionally, if a taxpayer applies for a grant, it must include in its application (or amended application) a Data Universal Numbering System number from Dun and Bradstreet (which is free) and, in order to receive actual payment of the grant, must register with the Central Contractor Registration.

Grants are not available for any Federal, State or local government (or any political subdivision, agency, or instrumentality), tax-exempt organization under Code Section 501(c), clean renewable energy bond lender, cooperative electric company, or any pass-through entity involving any of these.

Click [here](#) for the text of Notice 2010-45.

Click [here](#) for the relevant text of the Affordable Care Act.

Click [here](#) for our prior alert discussing this program and other tax provisions affecting life sciences companies in the Affordable Care Act.

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