

Alert 10-120

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IRS Issues Guidance on Application Process for New Tax Credits and Cash Grants for Small Biotech Companies

The *Patient Protection and Affordable Care Act of 2010* included a tax subsidy for eligible small biotech companies known as the "qualifying therapeutic discovery project" credit. The tax subsidy consists of \$1 billion of tax credits ("Credits") or, at the taxpayer's election, cash grants ("Cash Grants") for "qualified investments" made by small biotech companies for the development of new therapies to prevent, diagnose and treat acute and chronic diseases.

On May 21, 2010, the Internal Revenue Service (the "Service") issued Notice 2010-45 (the "Notice"), which established the program and announced the procedures for applying for Credits or Cash Grants. The Notice sets forth the guidelines for the program and also includes "Appendix A" (the "Appendix"), which summarizes the submission information that will be required on the forthcoming application form. Most importantly, the Appendix includes a detailed description of the written narrative known as the "Project Information Memorandum" that must be submitted along with the application form. A copy of the Notice and Appendix can be found at www.ustreas.gov/press/releases/tg712.htm.

Background

Section 48D of the Internal Revenue Code of 1986, as amended (the "Code") provides for a Credit or, at the taxpayer's election, a Cash Grant, equal to 50 percent of certain expenses paid or incurred by an eligible taxpayer in taxable years beginning in 2009 and 2010 with respect to any "qualifying therapeutic discovery project." A "qualifying therapeutic discovery project" is a project that is designed:

- To treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or by carrying out research protocols, for the purpose of securing FDA approval of a product under section 505(b) of the Food, Drug, and Cosmetic Act (new drug applications), or section 351(a) of the Public Health Service Act (biologic license applications);
- To diagnose diseases or conditions, or to determine molecular factors related to diseases or conditions, by developing molecular diagnostics to guide therapeutic decisions; or
- To develop a product, process or technology to further the delivery or administration of therapeutics.

An "eligible taxpayer" is any taxpayer that employs not more than 250 employees in all of its businesses (including the businesses of its affiliates). Certain taxpayers are not eligible for the Credit or Cash Grants, including any federal, state or local government, any tax-exempt organization under section 501(c)(3) of the Code, and certain foreign entities.

The Credit or Cash Grant is equal to 50 percent of a taxpayer's "qualified investment" in the qualifying therapeutic discovery project. For more information about the eligibility requirements and what expenses are eligible for the Credit or Cash Grants, see our prior Tax Alert dated April 15, 2010 ([Reed Smith Alert 10-077](#)).

The Credits and Cash Grants are to be awarded by the Treasury Department in consultation with the Department of Health & Human Services ("HHS") pursuant to a competitive application process based on criteria set forth in Code Section 48D. The statute limits to \$1 billion the total amount of Cash Grants and Credits that may be allocated under the program.

Application Procedure

The Notice sets forth the application procedure for the primary 2009-2010 allocation round of Section 48D Credits and

Cash Grants. It states that a separate application must be submitted for each qualifying therapeutic discovery project. Taxpayers are required to submit an application for certification to the Service by July 21, 2010. The application must be submitted on IRS Form 8942, "Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program." The Notice states that IRS Form 8942 will be released no later than June 21, 2010. An application for certification may include a project's costs for taxable years beginning in 2009 or 2010, or both.

Each application will be subject to a preliminary review that will enable the Service to determine whether an applicant is an eligible taxpayer and whether the application is complete. Preliminary review of applications will end on September 30, 2010. Applications that pass the preliminary review will be considered submitted for purposes of Section 48D on October 1, 2010. The Service will approve or deny a taxpayer's application for certification no later than October 29, 2010, and will notify the taxpayer by letter of its decision. The letter will state the amount of qualified investment that is certified as eligible for the Credit or Cash Grant and the amount of the Credit or Cash Grant allocated to the taxpayer (this amount will equal 50 percent of the amount of qualified investment certified as eligible).

Submission requirements for the application are detailed in the Appendix of the Notice. In addition to IRS Form 8942, the application must include a Project Information Memorandum. The Appendix describes the content and format of information to be provided by an applicant, including the questions that must be answered in the Project Information Memorandum. There are strict word limits on the required statements in the Project Information Memorandum, as well as required margin, font and page sizes. The Service and HHS may reject an application that does not follow the instructions regarding the organization and content of the application.

Review of Applications

The Notice states that HHS will be responsible for the initial review of the applications. We understand that the National Institutes of Health will be conducting the scientific review portion of the application review process.

The Service will certify an eligible taxpayer's qualified investment associated with a qualifying therapeutic discovery project if:

- HHS determines that the taxpayer's project is a qualifying therapeutic discovery project;
- HHS determines that the taxpayer's projects shows *reasonable potential*:
 - To result in new therapies that either (i) treat areas of unmet medical need, or (ii) prevent, detect or treat chronic or acute diseases;
 - To reduce long-term health care costs in the United States; or
 - To significantly advance the goal of curing cancer within the next 30 years; and
- The Service determines that the taxpayer's project is among those projects that have the *greatest potential* (a) to create and sustain (directly or indirectly) high-quality, high-paying jobs in the United States, and (b) to advance United States competitiveness in the fields of life, biological and medical sciences.

Limitation on Amount Certified

The Notice contains two limitations on the amount that the Service will certify for any specific project. These limitations are in addition to the \$1 billion statutory limit on the total amount of Credits and Cash Grants to be allocated under Section 48D.

- The Service will certify an equal amount of qualified investment for each project that is certified. This means that *each project that is certified will receive the same amount of Credit or Cash Grant*, regardless of the size of the project. However, in no case will the Service certify more than the amount of the qualified investment attributable to a project. In that case, the unused certification amount for that project will be reallocated among all the other projects receiving a certification for only a portion of their qualified investments.
- No single taxpayer will be allocated more than \$5 million in Credits and Cash Grants in the aggregate for 2009 and 2010, regardless of the number of projects for which the taxpayer has submitted applications.

Taxpayers may submit more than one project for consideration. Because each project that is certified will receive the same amount of Credit or Cash Grant, taxpayers who submit applications for more than one project may be able to take maximum advantage of the amount of Credits and Cash Grants available, subject to the overall \$5 million per taxpayer limit.

Evaluation Criteria

The Appendix also identifies the evaluation criteria to be used by the Service and HHS in the review of applications for certification. Some examples of such evaluation criteria are as follows:

- The number of full-time and part-time employees and contractors in the United States whose work is directly billed to the project, and the average salaries of these employees and contractors. The Appendix states that the Service will review this information in order to determine which projects have the greatest potential to create and sustain high-quality, high-paying jobs in the United States.
- Whether, as of the date the application is submitted, the project is active, terminated or suspended. The Service will review this information in determining which projects have the greatest potential to advance United States competitiveness in the fields of life, biological and medical sciences. A project that has been terminated or suspended because the project failed a clinical trial, failed a pre-clinical research milestone, or failed to secure FDA licensure, will be determined to have insufficient potential and thus will be determined to be ineligible for certification.
- Whether the project:
 - Will produce new or significantly improved technology, or a new application or significant improvement to existing technology, as compared with commercial technologies currently in service; and
 - Is expected to lead to the construction or use of a contract production facility in the United States in the next five years.

The Service will review this information in determining which projects have the greatest potential to advance United States competitiveness in the fields of life, biological and medical sciences.

Start Preparing Now

Although the application form will not be released until June 21, we expect that IRS Form 8942 will contain the same information requirements that are set forth in the Appendix of the Notice. We highly recommend that our clients begin working on their applications in advance of the issuance of IRS Form 8942; in particular, clients should be identifying eligible costs and drafting the Project Information Memorandum. By starting now, taxpayers will have additional time to prepare their applications by the July 21 deadline. We also expect that the application review process will be highly competitive and that the entire \$1 billion will be allocated in this initial round. We do not anticipate that there will be any subsequent application rounds. A similar program last year for manufacturers of renewable energy property was oversubscribed, and credit availability was exhausted in the first application round.

Reed Smith is ready to assist clients with the preparation of their applications, particularly the Project Information Memorandum. We have previously assisted clients in the preparation of successful applications for a number of newly created federal tax credit and grant programs, including last year's tax credit program for manufacturers of renewable energy property. We can assist clients by identifying key elements of the award criteria, working within the word limitations on the presentation of information, and advising on ways to maximize the chances of success.

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors, or the Reed Smith attorney with whom you regularly work.

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→ [Ruth N. Holzman](#)
Partner
Century City
+1 310 734 5214

→ [Angelo Ciavarella](#)
Partner
New York
+1 212 549 0339

→ [Paul J. Jaskot](#)
Partner
Philadelphia
+1 215 851 8180

→ [Michael Sanders](#)
Partner
Century City
+1 310 734 5232

→ [Donald C. Reinke](#)
Partner
San Francisco
+1 415 659 5989

→ [Richard Scudellari](#)
Partner
Silicon Valley
+1 650 352 0514

→ [Nanette W. Mantell](#)
Partner
Princeton
+1 609 514 8542

→ [Christopher L. Rissetto](#)
Partner
Washington, D.C.
+1 202 414 9206

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