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IRS Announces One-Month Application Period for Tax Credits and Grants Under the Qualifying Therapeutic Discovery Project Program

As part of the Patient Protection and Affordable Care Act of 2010, a Qualifying Therapeutic Discovery Project Program (the "Program") was established pursuant to Section 48D of the Internal Revenue Code (the "Code"). The Program allows a qualifying taxpayer to obtain tax credits and/or grants for fifty percent (50%) of the taxpayer's qualified investments in qualifying therapeutic discovery projects made during the taxpayer's 2009 and 2010 taxable years, as certified by the Internal Revenue Service ("IRS"). On May 21, 2010, the IRS issued **Notice 2010-45** [<http://www.irs.gov/pub/irs-drop/n-10-45.pdf>], advising taxpayers regarding the rules and procedures that will govern the Program and, most importantly, notifying taxpayers **that they will have only until July 21, 2010 to submit an application for the necessary certification from the IRS.** Although the application for certification has not yet been published, this Alert summarizes certain highlights of the Program and the certification requirements so that interested clients can begin to assemble the information necessary to timely file a complete and compelling application.

Overview of Credit/Grant

In order to apply for certification of a "qualified investment" in a "qualifying therapeutic discovery project," the following criteria must be satisfied:

- **Small Business.** The taxpayer must not employ more than 250 employees (both full-time and part-time), inclusive of employees of entities who are in the same control group or affiliated service group as the taxpayer. Leased employees are not counted for this criterion.
- **Qualifying Therapeutic Discovery Project.** The project for which the investment was made and/or is to be made must be designed to: (i) 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 approval of a product under section 505(b) of the Federal Food Drug and Cosmetic Act or Section 351(a) of the Public Health Service Act; (ii) diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions; or (iii) develop a product, process or technology to further the delivery or administration of therapeutics.

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- **“Qualified Investment.”** A qualified investment is the aggregate of the expenses paid or incurred by the taxpayer during its 2009 or 2010 taxable year that are necessary for, and directly related to, the conduct of a qualifying therapeutic discovery project and that have been certified by the IRS. Such expenses may not include: (i) “facility maintenance expenses,” which are defined to include mortgage or rent payments, insurance payments, utility and maintenance costs, and the cost of employing maintenance personnel; (ii) interest expenses; (iii) remuneration for the chief executive officer of the applicant or of those employees whose compensation must be reported to shareholders under the Securities Exchange Act of 1934; (iv) certain indirect service department costs; and (v) any other expense as determined by the IRS. A credit also will not be allowed for any investment expense for which bonus depreciation is allowed. [Ed. note. Please note that the receipt of a credit or grant for a qualified investment under the Program could have an impact on the tax reporting associated with expenditures and assets relating to the underlying qualified investment, including the calculation of depreciable basis, deductibility of expenses, etc.]

Application Process

As noted above, the amount of qualified investment in a qualifying therapeutic discovery project must be certified by the IRS. The process for the submission and consideration of an application for certification, which will be reviewed by the IRS in coordination with the Department of Health and Human Services (“HHS”), will involve the following:

- **Application Form.** The application must be made on a Form 8942, *Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program*. The Form 8942 will be published by the IRS no later than June 21, 2010. A separate application must be filed for each project for which the taxpayer seeks a credit or grant.
- **Application Due Date. The Form 8942 must be delivered to the IRS no later than July 21, 2010.** No advantage is given to an application submitted early. The general rules governing the delivery of tax returns will apply, so that submissions postmarked on or before July 21st will be considered timely. If a significant change is made in a project after an application is submitted, the taxpayer must immediately notify HHS. The IRS or HHS may solicit additional information after the application deadline, but a taxpayer may not supplement an application.
- **Special Grant Application Requirements.** In order to apply for a grant rather than a credit, the applicant must affirmatively elect on Form 8942 to apply for a grant for 2009 only, 2010 only or for both 2009 and 2010. An election to apply for a grant must include the applicant’s Data Universal Numbering System (DUNS) number from Dunn and Bradstreet, and the applicant must register with the Central Contractor Registration. A DUNS number may be obtained at no cost by calling the dedicated toll-free DUNS number request line at 1-866-705-5711. To register with the Central Contractor Registration, go to www.ccr.gov/startregistration.aspx. In the case of the 2009 taxable year, the applicant can request a grant in lieu of a credit by filing an amended Form 8942 by the later of September 30, 2010 or the due date (including extensions) for the filing of the applicant’s tax return for the 2009 taxable year. In the case of the 2010 taxable year, the applicant may request a grant in lieu of a credit by filing an amended Form 8942 by no later than the due date (including extensions) for the filing of the applicant’s tax return for the 2010 taxable year.

- **Limitations on Credits/Grants.** In accordance with Code § 48D, the IRS will certify no more than an aggregate of \$2 billion of qualified investments, such that up to \$1 billion of credits and grants will be available for all taxpayers for the 2009 and 2010 tax years combined. The IRS has indicated that it will allocate the grant/credit pool pro rata among chosen applicants, and no one taxpayer will be allocated more than an aggregate of \$5 million in credits and/or grants for 2009 and 2010.
- **Review Standard.** The IRS will certify a taxpayer's qualified investment associated with a qualifying therapeutic discovery project only if HHS determines that the taxpayer's project: (i) is a "qualifying therapeutic discovery project"; (ii) "shows reasonable potential (a) to result in new therapies to . . . treat areas of unmet medical need, or . . . to prevent, detect, or treat chronic or acute diseases and conditions, (b) to reduce long-term health care costs in the United States, or (c) to significantly advance the goal of curing cancer within the 30-year period beginning on May 21, 2010;" and (iii) the IRS determines that the taxpayer's project is among those projects that have the greatest potential "(a) to create and sustain (directly and 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."
- **Review Process.** A preliminary review of the applications will be completed by September 30, 2010. A preliminary round of approvals and denials will be mailed to applicants no later than October 29, 2010. The IRS reserves the right to conduct additional rounds of certifications (for example, if a sufficient amount of qualified investments are not certified). There is no right to a conference or appeal from the decision made by the IRS, and applications will not be returned.

Application for Certification

Although the Form 8942 has yet to be published, IRS Notice 2010-45 provides important details concerning what information and additional submissions will be required to apply properly for the certification of a qualified investment:

- **Form 8942.** The Form 8942 will solicit the following information under penalties of perjury:
 - ◆ The applicant's general information, including name, address and taxpayer identification number;
 - ◆ The name of a contact person, who either has the legal authority to bind the applicant or has been granted such authority via a properly-executed Form 2848, Power of Attorney and Declaration of Representative;
 - ◆ The type of entity and its ownership;
 - ◆ The number of the applicant's full-time and part-time employees;
 - ◆ Whether the applicant is requesting a credit or a grant in lieu of a credit;
 - ◆ A description of the applicant's 2009 and 2010 qualified investments;
 - ◆ The number and average salary of all full-time and part-time employees in the United States whose work is directly billed to the project and the average monthly billing;

- ◆ The number of United States contractors being paid for work on the project and the average monthly compensation and hours of the contractors;
 - ◆ The status of the project (active, terminated or suspended) as of the date of the application; and
 - ◆ Whether the project will produce new or significantly improved technology, or a new application or significant improvement to existing technology, and whether it is expected to lead to construction of a contract production facility located in the United States in the next five years.
- **Project Information Memorandum.** The applicant must attach to the Form 8942, a Project Information Memorandum (“PIM”) which will be used by HHS to determine whether the applicant’s project is a “qualifying therapeutic discovery project.” The PIM must follow strictly the format described in IRS Notice 2010-45, and respond fully to the eleven questions set forth in the form. As part of the PIM, an applicant will be required to prepare and submit a series of written responses, each of which may not exceed 250 words. Those responses must:
 - ◆ Provide an overview of the project, including a description of the product, process or technology under development and, if the project involves a new therapy, a description as to why the therapy is novel.
 - ◆ Explain the scientific rationale, based on prior conceptual and empirical work, which supports the applicant’s belief that the project will lead to the outcome identified by the applicant.
 - ◆ Describe the stage of development of the project, including a description of pre-clinical and clinical results that are relevant to the proposal.
 - ◆ Describe the resources, management experience and organizational capacity of the applicant and how those resources, experience and capacity will support successful completion of the project.

If the PIM will contain information the applicant considers to be trade secrets, confidential, privileged or otherwise exempt from disclosure under the Freedom of Information Act, the applicant must place a form claim of exemption on the first page of the PIM, and specify the page or pages of the application to be restricted, and may insert a similar request where the proprietary information is actually located in the PIM.

- **Disclosure Request.** Due to a language glitch in the health care legislation, the IRS has determined that it can, and will, upon making a certification, publicly disclose (i) in the case of a grant made for the 2009 tax year, the identity of the applicant, the amount of the grant and the description of the investment with respect to which the grant was made; and (ii) in the case of a grant made for the 2010 tax year, or in the case of a credit for either 2009 or 2010 tax year, the identity of the applicant and the amount of the credits. So that it may provide the same information with respect to all applicants, the IRS is requesting that an applicant, other than an applicant only applying for a grant for the 2009 year, file a form consent permitting disclosure of a description of the type and location of the project with respect to which the grant or credit was allowed. IRS Notice 2010-45 states that the consent is not required.



Taxpayers considering filing an application for a credit or grant under the Qualifying Therapeutic Discovery Project Program are encouraged to consult with their tax advisors as soon as possible so that they may understand fully the requirements, benefits and burdens associated with the Program and so that they may promptly begin to assemble the information for an application. Please contact any member of our Tax Practice Group if we can be of any assistance in that regard.

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