

## Treasury Department Releases New Guidance for Therapeutic Discovery Credit or Grant Program

June 2010

On May 21, 2010, the U.S. Treasury Department published Notice 2010-45 (the "Notice") which provides guidance and clarification for companies with 250 employees or less to apply for § 48D certification of the Therapeutic Discovery Credit or Grant. As part of the review process for research projects, the Department of Health and Human Services ("HHS") will evaluate each project for its potential: (1) to result in new therapies to treat areas of unmet medical need, or result in new therapies to prevent, detect, or treat chronic or acute diseases and conditions; (2) to reduce long-term health care costs in the United States; or (3) to advance the goal of curing cancer significantly within the 30-year period beginning on May 21, 2010; and the Internal Revenue Service ("IRS") will determine if (4) the company's project is among those projects that have the greatest potential to create and sustain (directly or indirectly) high quality high-paying jobs in the United States and increase U.S. competitiveness in the fields of life, biological, and medical sciences to produce new therapies or reduce health care costs. Only projects that show a reasonable potential to meet these goals will be certified by the IRS as eligible for the credit or grant, which covers up to 50 percent of the cost of qualifying biomedical research. There is a cap on the credit or grant of \$5 million in total per company.

The Notice sets out the procedures for a company to follow to request § 48D certification. For the initial primary round of applications, a company may file its application for § 48D certification beginning with the date the application form (Form 8942) is released by the IRS up and through July 21, 2010. The Notice provides that a company must file a separate application for each qualifying therapeutic discovery project for which it is seeking certification of a qualified investment. Each application will be subject to a preliminary review, which will enable the IRS to determine whether the applicant is an eligible company and whether

the application is complete. The IRS and HHS reserve the right to request clarifications and supplemental information from the applicants. All applications submitted by that time will be treated as submitted on October 1, 2010, when the IRS will begin its formal 30-day review process for all applications.

### Contents of Application

The application itself consists of three parts: 1) Form 8942, "Application for Certification of Qualified Investments Eligible For Credits and Grants Under the Qualifying Therapeutic Discovery Project Program," which has yet to be developed but will be released no later than June 21, 2010; 2) Project Information Memorandum; and 3) a Consent to Public Disclosure, if applicable.

### Form 8942

Form 8942 will require:

- basic applicant information,
- the amount of full time and part time employees for the 250-employee test,
- if a company is seeking a grant instead of a credit,
- a description of the investments for 2009, 2010, or both and investment amounts,
- information on employees and contractors on the project to determine potential for creating jobs,
- whether at the time of submission the project is active, terminated or suspended, and whether the project will produce significantly improved technology or produce a significant improvement to an existing technology,
- and if the project is expected to lead to the construction or use of a contract production facility in the United States in the next five years.

### Project Information Memorandum

The Project Information Memorandum contains the technical portion of the application, which will be evaluated by HHS. A company must follow the specified format

of the Project Information Memorandum. A company must check yes or no to specific questions and must provide written narratives with respect to certain questions, including narratives that support the checked yes answer. There are word limitations, which will be strictly adhered to and any words beyond the limitation will be disregarded. No material can be incorporated by reference. Brochures and other presentations are not permitted as part of the application submission and will not be considered.

A company must provide an overview of the project requested, including a description of the product, process, or technology under the development. The description may not exceed 250 words. There are also questions requiring yes or no answers. If a company answers yes to the question, then the company must provide a short statement no more than 50 words supporting its answer. The first four questions are based on a company's project satisfying the definition of a qualifying therapeutic discovery. A company only needs to only answer yes to at least one question. The next four questions are based on the reasonable potential selection criteria to ascertain if the project is likely to result in one or more new therapies, which are expected to treat areas of unmet medical need or to prevent, detect or treat chronic or acute diseases. These questions also address the possibility of reducing long term health care costs in the United States as well as if the project is likely to significantly advance the goal of curing cancer within the next 30 years. The next set of questions pertain to the project's scientific rationale, development stage, and resources leading to project completion. For questions pertaining to scientific rationale, a company is allowed to submit up to five literature citations, which will not be counted towards the word count limitations.

Due to the public disclosure of certain application information, a company may

assert a claim of exemption with respect to information that it considers to be trade secrets, confidential, privileged or otherwise exempt from disclosure under the Freedom of Information Act. A company must assert specific text identified in the Notice and specify which pages of the application are restricted. This text will not be counted towards the word count limitations specified in the Project Information Memorandum.

#### **Consent to Public Disclosure**

The IRS requests that each company that applies for a credit or for a grant for a taxable year beginning in 2010, submit with the application for § 48D certification a declaration found in Appendix B of the Notice, which consents to the IRS' disclosure of the type and location of the project that is the subject of the application for § 48D qualifying therapeutic discovery project certification in the event that its project receives an allocation. The IRS will not publish any return information with respect to applications that are not awarded an allocation of the qualifying therapeutic discovery project credit or grant.

#### **Certification Process**

Both HHS and IRS are involved in the certification process. HHS will review the technical scientific and health aspects while the IRS will review the economic aspects, i.e. U.S. job creation and increase of U.S. competitiveness and leadership in medical advances.

The project's investments may occur in 2009, 2010 or both. If a project would otherwise receive certification for an amount of qualified investment that exceeds the qualified investment that is attributable to the project, then the unused certification amount will be apportioned equally among all other projects receiving a certification for only a portion of their qualified investments. If a project certification exceeds the amount actually spent, there will be a reduction in credit to the company to the extent of the credit attributable to the amount not spent.

In the primary 2009-2010 allocation round, the IRS will approve or deny the company's application for § 48D certification no later

than October 29, 2010. The company must inform the IRS if the plans for a qualifying therapeutic discovery project change in any significant respect any time prior to receiving certification. Furthermore, IRS and HHS determinations can not be appealed.

#### **Grants in Lieu of Credits**

For taxable years beginning in 2009 or 2010, a company must affirmatively request a grant in lieu of a credit. To request a grant, a company needs to include its Data Universal Numbering System ("DUNS") number from Dun and Bradstreet. In addition, the company must also be registered with the Central Contractor Registration ("CCR").

When an application for certification of qualified investment in a qualifying therapeutic discovery project is approved and the company has requested a grant in lieu of a credit, the IRS will send a letter to the company in the same manner as a company that receives a tax credit certification.

Due to the short window of opportunity and the word limitation requirements, companies are advised to be careful in drafting clear, concise, and convincing descriptions and narrative answers in order to maximize their chance of obtaining a credit or grant.

To learn more about the procedures to apply for a Qualifying Therapeutic Discovery Project Credit or Grant or to seek assistance in filing your company's application, please contact your Burns & Levinson attorney or Jennifer B. Green at 617.345.3324 / [jgreen@burnslev.com](mailto:jgreen@burnslev.com).