

## Update for Small Biotechs and Pharmas: Treasury Publishes Guidelines for Qualifying Therapeutic Discovery Project Program, Sets July 21 Deadline for Applications

May 28, 2010

On May 21, 2010, by Internal Revenue Service Notice 2010-45 ("Notice"), the U.S. Department of the Treasury ("Treasury") announced the establishment of the Qualifying Therapeutic Discovery Project program pursuant to Section 9023(a) of the Patient Protection and Affordable Care Act of 2010 ("Affordable Care Act"). Under the Qualifying Therapeutic Discovery Project program, the Internal Revenue Service ("the Service"), in consultation with the Department of Health and Human Services ("HHS"), will certify \$1 billion in nonrefundable tax credits or, if elected, grants in lieu of credits for qualified investments in projects that show significant potential to produce new and cost-saving therapies, create and sustain good jobs, and increase US competitiveness in the fields of life, biological and medical sciences. The Notice also provides guidance to applicants with respect to the eligibility requirements, application procedures and key dates, and selection criteria for qualifying therapeutic discovery project credits. These guidelines, terms and conditions, as well as detailed information with respect to the format and content of applications for certification, are available at <http://www.irs.gov/pub/irs-drop/n-10-45.pdf>.

### Program Overview

The Affordable Care Act authorized the Qualifying Therapeutic Discovery Project program through its creation of a new section of the Internal Revenue Code ("Code"), section 48D, which provides for an investment tax credit to certain companies for the cost of expenses paid or incurred during the 2009 or 2010 year for qualifying therapeutic discovery projects. According to Treasury Secretary Tim Geithner, the goal of this credit is to "help advance research to find life-saving treatments and help US companies lead the way in innovative medical discoveries." The amount of the credit is up to 50 percent of the cost of qualifying biomedical research. Compensation for high-ranking executives, interest expenses, facility maintenance expenses and other overhead and indirect costs associated with operating a business do not qualify for the credit. The credit is only available to companies with fewer than 250 employees. A grant for qualified investments in therapeutic discovery projects in lieu of the tax credit is also available, thereby allowing small- to medium-sized start-up companies that are not able to claim, or are prevented from claiming, tax credits to benefit as well. To obtain the credit, qualified investments

must be certified by the IRS. The Affordable Care Act gave Treasury 60 days to work in consultation with HHS to establish a program to consider and award certifications for qualified investments. Under the program as outlined in the Notice, certifications will be issued and credits or grants up to the total credit amount of \$1 billion will be allocated on a *pro rata* basis in annual rounds based on applications for certification filed with the Service. A primary allocation round will be conducted to issue certifications for both qualified investments made in tax years beginning in 2009 and qualified investments made in tax years beginning in 2010 and, if any portion of the \$1 billion remains unallocated after the primary round, additional rounds may be conducted. The primary 2009-2010 allocation round runs from the date the application form (Form 8942, "Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program") is made publicly available, which will be no later than June 21, 2010, and ends 30 days later, on July 21, 2010.

### **Application Procedures and the Allocation Process**

For the primary 2009-2010 allocation round, an applicant must submit for each project that it sponsors: (1) a completed Form 8942, (2) a Project Information Memorandum and, if the applicant elects to consent to certain limited disclosure, (3) a properly executed copy of a "Consent to Public Disclosure of Certain Qualifying Therapeutic Discovery Project Program Application Information." These documents comprise the application for certification; no additional written submissions or requests to make oral presentations will be accepted if not solicited by the Service or HHS.

Although the Form 8942 is not yet available, Appendix A of the Notice outlines 11 items of information that the form will solicit, including (1) whether the applicant is requesting a grant in lieu of a credit, and (2) describing whether the project (a) will produce a new or significantly improved technology, or a new application or significant improvement to existing technology, as compared to commercial technologies currently in service, and (b) is expected to lead to the construction or use of a contract production facility in the US in the next five years. This latter information will be used by the Service in determining which projects have the greatest potential to advance US competitiveness in the fields of life, biological, and medical sciences. Appendix A also outlines the format and describes the content of the Project Information Memorandum, which will be reviewed by HHS in order to determine whether a project is a qualifying therapeutic discovery project and whether the applicant has shown that its project shows a reasonable potential to meet one or more of the selection criteria specified in Code section 48D.

In order to be considered timely, the application package must be postmarked no later than July 21, 2010. Thus, it is not a race to submit

an application. Each timely-filed application will first be subject to a preliminary review, which will enable the Service to determine whether the applicant is an eligible company and whether the application is otherwise complete. The Service will complete its preliminary review of applications on September 30, 2010. Then, upon further review of the applications by the Service and HHS, credits or grants will be awarded *pro rata* to applicants that the Service and HHS determine meet certain certification conditions. The Notice provides additional limitations on the amount of the credit or grant. Those limitations are that (1) no one applicant will be certified for more than \$5 million in credits or grants for 2009 or 2010, regardless of the number of projects the applicant sponsors and (2) no applicant will receive a credit or grant for more than it requested, so that, for example, if an applicant requested \$500,000 and is allocated \$1 million, the \$500,000 difference will be redistributed among the other applicants who received only a portion of the credit or grant they requested.

The process, therefore, is based on the number of applicants in the qualified pool as determined by the Service and HHS and not the amounts requested. It also takes out the need for the Service and HHS to weigh diverse therapies, products and technologies against one another; instead, each application is evaluated on its own merits. The process clearly favors those eligible companies who request smaller credit or grant amounts. According to the Notice, 1,200 applicants are anticipated to file applications, which makes it likely that the \$1 billion total amount will be depleted quickly, each applicant will receive less than \$5 million, and there will not be additional allocation rounds.

Because the Affordable Care Act directs the Service to approve or deny applications within 30 days of the submission of the application, the Service deems all applications submitted on October 1, 2010, the day after the preliminary review ends, and the Service will approve or deny applications no later than October 29, 2010, notifying applicants, by letter, of its decision. For certified projects, the acceptance letter will state the amount of qualified investment that is certified as eligible for the credit or grant and the amount of the credit or grant allocated to the applicant for the applicant's project(s). In the case of grant awards, detailed rules are provided in the Notice regarding the timing of the grant payment for applicants with tax years beginning in 2009 and in 2010.

### **Certification Conditions**

The Service and HHS both have a role in evaluating the applications. Consistent with the selection criteria set forth in Code section 48D(d), the Notice states that only those projects that meet the following three conditions will receive a certification for all or a portion of their qualified investment:

This memorandum is intended only as a general discussion of these issues. It is not considered to be legal advice. We would be pleased to provide additional details or advice about specific situations. For additional information on this important topic, please feel free to call upon your Dewey & LeBoeuf relationship partner.

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1. HHS determines that the applicant's project is a qualifying therapeutic discovery project;
2. HHS determines that the applicant's project shows reasonable potential (a) to result in new therapies to treat areas of unmet medical needs, or to prevent, detect or treat chronic or acute diseases and conditions, (b) to reduce long-term health care costs in the US, or (c) to significantly advance the goal of curing cancer within the 30-year period beginning on May 21, 2010; and
3. The Service determines that the applicant'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 US, and (b) to advance US competitiveness in the fields of life, biological, or medical sciences.

Appendix A of the Notice provides additional details regarding each of these determinations.

### **Additional Provisions**

- The Service is required to publish the results of the allocation process and disclose the identity of the approved applicants and the amount of credits or grants allocated to each applicant's project. Additionally, upon making a certification with respect to applicants that have either elected a grant for the 2009 tax year or provided the executed copy of the consent form, the Service will also publish the type and location of the project in the event the project receives an allocation.
- An applicant does not have a right to a conference relating to any matters under the Notice, and an applicant does not have a right to appeal the decisions made under the Notice (including the amount of credit allocated to the project and whether or not to certify the project) to any official of HHS or the Service or Treasury.
- The at-risk rules in Code section 49, as well as the recapture and other special rules in Code section 50, apply.

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