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Therapeutic Discovery Project Tax Credit and Cash Grants of up to $5 million — Application Procedures Released in IRS Notice 2010-45

IRS Notice 2010-45 was released on May 21, 2010 describing the application procedures for the new $1 billion investment tax credit and cash grants program for certain drug development or other medical advances by taxpayers not employing more than 250 employees.

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Established by the Patient Protection and Affordable Care Act of 2010, "QTDP Credits" and "QTDP Grants" under Internal Revenue Code §48D are available for "qualifying therapeutic discovery projects." This Client Advisory highlights the key provisions and required information for the Therapeutic Discovery Project Tax Credit and Cash Grants Application.

QTDP Program Generally

The QTDP Credit is limited to 50% of the certified costs incurred in 2009 and 2010 of a qualifying therapeutic discovery project. QTDP Grants are also available for qualifying therapeutic discovery projects in lieu of the QTDP Credit. These QTDP Grants would allow early stage pre-revenue companies and/or pre-taxable income companies to benefit from this new tax program. In order to make funds available to a greater number of companies, there is a limit of $5 million per taxpayer in QTDP Credits or QTDP Grants in the aggregate for 2009 and 2010, regardless of the number of projects the taxpayer sponsors. See Client Advisory dated April 2010 for more information on the Therapeutic Discovery Project Tax Credit and Cash Grants Program.

QTDP Application Deadlines and Procedures

The QTDP application form will be released on the IRS website by June 21, 2010. Completed QTDP applications then must be filed by July 21, 2010.

IRS Notice 2010-45 provides the procedures under which an eligible taxpayer may apply for certification from the IRS of a QTDP qualified investment. QTDP applications will be made on Form 8942, "Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program."

The IRS and U.S. Department of Health and Human Services ("HHS") will review all applications submitted by eligible taxpayers. HHS will specifically review the Project Information Memorandum portion of the application in which the taxpayer provides the narrative description of the therapeutic discovery project which will be assessed against the statutory definitions and goals outlined in Internal Revenue Code §48D. The IRS will approve or deny the QTDP application by October 29, 2010 and will notify the taxpayer, by letter, of its decision. QTDP Grants will be paid 30 days after the last day of the 2010 taxable year.

Notice 2010-45 Appendix A - Content of Application

Appendix A describes the content and format of information to be provided in the forthcoming QTDP application form. This allows taxpayers to assess evaluation criteria to be used by the IRS and HHS in the review of QTDP applications and prepare responses to the questions that must be answered in the required Project Information Memorandum.

The Project Information Memorandum must include an overview of the project, a description of why a therapy is novel, a statement of scientific rationale for the project, the research and development plan for the project, a description of the stage of the development of the project, and an outline of the financial and organization plan of the project demonstrating an applicant's capacity to complete the project. The Project Information Memorandum must explain why the project meets the statutory definition of a "qualifying therapeutic discovery project". Appendix A highlights the following types of qualifying projects:

- Projects designed to treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, or clinical studies or carrying out a clinical or other research protocol for the purpose of obtaining approval of a product under one of two statutory provisions—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (a new drug application) or Section 351(a) of the Public Health Service Act (PHSA) (a biologic license application).
- Projects designed to diagnose a disease or condition, whether or not it determines molecular factors or is a molecular diagnostic (e.g. point of care diagnostics for infectious agents).
- Projects designed to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions (e.g. a test that would determine which patients with a particular disease or condition would be likely to respond best to a particular drug or device).
- Projects designed to develop a product, process, or technology to further the delivery or administration of therapeutics, which includes drugs and medical devices as those terms are defined in Section 201(g) and (h) of the FFDCA, 21 U.S.C. 321(g) and (h). Biologics that are licensed under the PHSA will generally be either drugs or medical devices.

Projects must also have a reasonable potential to meet one or more of the statutory goals of: (i) providing novel therapies; (ii) treating areas of unmet medical need, or preventing, detecting, or treating chronic or acute diseases or conditions; (iii) reducing long-term health care costs in the United States; or (iv) significantly advancing the goal of curing cancer within the next 30 years.

After HHS determines that the project is a qualifying project and shows a reasonable potential to achieve one or more of the statutory goals, the IRS will only certify projects that have the greatest potential to:

- create and sustain (directly or indirectly) high quality, high-paying jobs in the U.S., and
- advance U.S. competitiveness in the fields of life, biological and medical sciences.

Taxpayers should also gather the description and amounts of qualified investments for 2009 and 2010, and 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 compensation data. A copy of Appendix A can be found at http://www.eapdlaw.com/files/upload/Notice2010-45AppendixA.pdf.

Note that this Client Advisory highlights only a few of the changes made by the Patient Protection and Affordable Care Act of 2010 that may affect your business planning. If you have any questions regarding the tax law changes summarized in this Advisory or other provisions of the Patient Protection and Affordable Care Act of 2010, and how these changes and provisions may affect your business, please contact one of the following members of our Tax Department listed below.

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