Application for Therapeutic Discovery Grant or Tax Credit Must Be Submitted by July 21

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On May 21, the Internal Revenue Service issued Notice 2010-45 ("IRS Notice") providing details on applying for the Qualifying Therapeutic Discovery Project Program ("QTDP Program") established by the Patient Protection and Affordable Care Act of 2010, including the application deadline of July 21, 2010. The $1 billion QTDP Program established both a tax credit ("QTDP Credit") and a grant ("QTDP Grant") for investments in 2009 and 2010 by small and mid-size companies developing therapeutic medical projects. This is an update to our May 13, 2010 underline publication on the QTDP Program.

Application Deadlines—The application timeframe under the QTDP Program is very limited—applications will be accepted between **June 21, 2010 through July 21, 2010**. The IRS Notice states that the complete application (including the Project Information Memorandum described below) must be postmarked on or before July 21, 2010 to be eligible. Applications postmarked after that date will be rejected.

Form of Application—Applications for the QTDP Program are to be made on Form 8942. **Form 8942 is not yet available.** The IRS has stated that it will make Form 8942 available no later than June 21. Although Form 8942 is not yet available, the IRS Notice sets forth the information that will be required by Form 8942. A separate Form 8942 must be filed with the IRS for each qualifying therapeutic discovery project for which a QTDP Grant or QTDP Credit is sought. Completion of the Project Information Memorandum will require significant information about each project.

Limit—No taxpayer will be entitled to receive more than a combined allocation of $5 million for both of QTDP Credits and QTDP Grants for 2009 and 2010.

Form of Project Information Memorandum—Each Form 8942 application must be accompanied by a Project Information Memorandum. The IRS Notice sets forth the required format and content of the memorandum, which includes both specific yes/no questions as well as provision for short narrative answers that support each yes answer and limited citations to scientific literature supporting the project claims. The rules for completion of the Project Information Memorandum include detailed requirements

with respect to the format, including word limitations and font and margin size. An application that fails to satisfy these requirements may be rejected or portions of the application may not be considered.

Other Requirements—Applicants for a QDTP Grant must satisfy certain additional requirements. First, the applicant must have a Data Universal Number System (DUNS) number from Dun and Bradstreet. This may be requested at no cost by applicants who do not yet have this number. Second, the application must register with the Central Contractor Registration, which can be done online.

Preliminary Review Deadline—The IRS Notice provides that a preliminary review of each application will be completed on September 30, 2010.

Award Deadline—The IRS will approve or deny applications for certification no later than October 29, 2010; successful applicants will be notified by mail of the amount of the qualified investment that is certified as eligible for the QTDP Credit or QTDP Grant.

Selection Criteria

Each application will undergo review by the Department of Health and Human Services ("**HHS**") to determine if it meets the QDTP award criteria. In its review, HHS will determine whether the application is for a project that is a qualifying therapeutic discovery project. If the project meets this hurdle, HHS will determine whether the project shows reasonable potential to (a) result in new therapies (i) to treat areas of unmet medical need, or (ii) 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 next 30 years. In approving applications for certification, the IRS will consider the results of the HHS review together with the potential of the project to create and sustain high-quality, high-paying jobs, and to advance U.S. competitiveness in the fields of life, biological, and medical sciences.

Action Needed

Completing the Form 8942 application and the Project Information Memorandum will require significant time and effort. Given the absolute deadline of July 21, anyone interested in the QTDP Program should immediately note the requirements set forth in the IRS Notice and begin putting together the application.

If you have any questions about the content of this client alert, please contact the Pillsbury attorney with whom you regularly work or the authors below.

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