White and Williams LLP

BioPharma and Tax and Estates News Alert, June 2010 www.whiteandwilliams.com

QUALIFYING THERAPEUTIC DISCOVERY PROJECT TAX CREDIT
PART II

By: Kevin S. Koscil, Esq.

On May 21, 2010, the IRS issued Notice 2010-45, which sets forth various details pertaining to the Qualifying Therapeutic Discovery Project (QTDP) tax credit. The QTDP credit (or grant) is a significant subsidy available to certain small businesses investing in selected types of biomedical research and development. This alert is provided as a follow up to our alert, "Qualifying Therapeutic Discovery Project Tax Credit" issued on May 18, 2010, which provides further details concerning the QTDP credit. This alert is primarily meant to summarize the implications of the most recent development: Notice 2010-45.

THE BASICS

Notice 2010-45 establishes the QTDP program: the procedures under which an eligible taxpayer applies for certification of a qualified investment as eligible for a QTDP credit or grant. As provided in § 48D of the Internal Revenue Code, the amount treated as a qualified investment cannot exceed the amount certified. The IRS will run the program in cooperation with the Department of Health and Human Services (HHS). It appears that HHS will mainly act as a gatekeeper, evaluating the scientific merits of projects, while the IRS will administer the other aspects of the program.

The IRS will certify an investment only if HHS determines that the applicant's project is a QTDP that meets the statutory selection criteria. This primarily involves an evaluation of the scientific merits of the project. Essentially, the project must exhibit reasonable potential to result in new therapies, reduce health care costs, or significantly advance the goal of curing cancer. Further, the project must be among those showing the greatest potential to create jobs in the U.S. and advance our country's competitiveness in certain scientific fields.

PROCEDURE AND TIMING

Applications will be made on Form 8942, which the IRS must issue no later than June 21, 2010. The form will be called "Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program" and, along with the accompanying instructions, will set forth the manner for submitting applications. A separate application must be made for each QTDP for which certification is sought and an applicant must alert the IRS of any significant change in the QTDP prior to certification.

The first credit allocation round will commence when the IRS releases Form 8942 (probably June 21) and will end on July 21, 2010 (postmark deadline). If part of the $1 billion allocated to the program remains after the first allocation round, then one or more additional allocation rounds may take place. The IRS must approve or deny an application within 30 days of submission; however, for this purpose, submission is deemed to be on October 1, 2010, the day after the preliminary review period ends. During the preliminary review period, the IRS will determine whether the applicant is an eligible taxpayer (see prior alert) and whether the application is complete.

An applicant may elect to be considered for a grant rather than a credit: a valuable option for an applicant that is not yet profitable and therefore cannot utilize a credit. An applicant for a grant must provide its Data Universal Numbering System number from Dun and Bradstreet and register with Central Contractor Registration.

Upon making a certification, the IRS will publicly disclose the identity of the applicant and the amount of the credit or grant. The IRS will also publish the type and location of a project if the

QUALIFYING THERAPEUTIC DISCOVERY…CONTINUED

applicant elects to receive a grant (instead of a credit) for the tax year beginning in 2009 or provides consent using the form appended to Notice 2010-45.

The IRS will certify a qualified investment as eligible for a QTDP credit only if (1) HHS determines that the project is a QTDP; (2) HHS determines that the project shows reasonable potential with respect to the statutory goals; and (3) IRS determines that the project is among those having the greatest potential to create and sustain high quality and high-paying jobs in the U.S. and advance U.S. competitiveness in life, biological, and medical sciences.

FORM 8942

Form 8942 will require general information, the number of employees employed by the applicant and corresponding salary information (for purposes of assessing the jobs created/sustained by the project), a description of the investment, a description of whether the project is active, terminated, or suspended, and an assessment of whether the project will lead to a significant advancement in technology or the construction or use of a contract production facility in the U.S. in the next five years (for purposes of evaluating potential enhancement to U.S. competitiveness). If the project has failed a clinical trial, for example, it will not have the requisite potential.

PROJECT INFORMATION MEMORANDUM

The applicant must also submit a Project Information Memorandum (PIM). HHS will evaluate the PIM to determine whether the project qualifies as a QTDP and whether it meets the goals set forth in the statute. Basically, the PIM is a checklist that precisely tracks the language of the statute. Yes/No questions must be answered and accompanied by short narratives. The IRS website will eventually provide a form PIM.

The PIM requires a 250-word project overview, including a description of the product, process or technology under development and an explanation of the novelty of any new therapy involved. Notice 2010-45 contains procedures for the protection of trade secrets and information that is privileged or confidential. The PIM will require answers to 11 questions, which will allow HHS and the IRS to determine whether the project qualifies as a QTDP and advances the statutory goals. Notice 2010-45 lists the questions and provides commentary related to each one. Since the questions track the statute (an analysis of which can be found in the prior alert), listing them here is unnecessary. Selected observations gleaned from reviewing the questions and the associated commentary are found below.

QUALIFICATION AS A QTDP

HHS will determine whether a project qualifies as a QTDP using the statutory requirements of § 48D. A few selected observations follow.

- A QTDP could involve conducting trials, studies, or research for the purpose of obtaining approval of a product under (A) § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (a new drug application) or (B) § 351(a) of the Public Health Service Act (PHSA) (a biologic license application). Generic drugs, dietary supplements and most cosmetics are not eligible.
- A QTDP could be a project designed to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions. On this requirement, the Notice elaborates: this might include, for example, a test to determine which patients with a particular disease or condition would be likely to respond best to a particular drug or device.
- A QTDP could be one designed to develop a product, process, or technology to further the delivery of therapeutics. For purposes of the credit, the term therapeutics is defined rather narrowly and with reference to the FFDCA and the PHSA. Basically, the technology must further the delivery or administration of a drug or medical device.

EVALUATION USING SELECTION CRITERIA

If the project meets the definition of a QTDP, the evaluation moves to the selection criteria. Essentially, the project must show reasonable potential to result in new therapies targeting unmet medical needs or chronic or acute diseases and conditions, reduce U.S. healthcare costs, or advance the goal of curing cancer within 30 years. The project must meet one or more of these statutory goals.

- Rather than a new therapy, the project could involve a significant enhancement related to the safety or effectiveness of an existing therapy.
- Regarding unmet medical needs or chronic or acute diseases and conditions, Notice 2010-45 refers to the following: novel influenza vaccine technology, broad spectrum anti-viral medications, novel antibiotics, and platform vaccine technologies.
- If the project will reduce long-term healthcare costs, the application should explain how this will be accomplished. This might include a description of how the project will lead to cost reductions and a reasonable estimate of savings and the potential for achieving them.

LIKELIHOOD OF SUCCESS

If HHS determines that the project is directed toward an appropriate goal under the statute, it will evaluate the project's

CONTRIBUTORS

KEVIN KOSCIL

Kevin Koscil is an associate in the Business Department and a member of the Tax, Pension and Estates Practice Group.

For more information, please contact Kevin at 215.864.6827 or email him at koscilk@whiteandwilliams.com.

.

.

likelihood of success by considering the scientific rationale underlying the project, the current stage of development, and the applicant's capacity to successfully complete the project.

- Applicants must explain the scientific rationale (based on prior conceptual and empirical work) supporting the belief that the project will lead to the desired outcome. Applicants must also explain the research and development plan and the scientific evidence, including a description of any peer review of the project, with appropriate citations.
- Applicants must describe the stage of development, including a description of relevant trial and testing results. This would include providing the status of an application to the Food and Drug Administration and of any other regulatory reviews or approvals. Applicants must describe the research and development strategy and summarize the project's schedule.
- An applicant must describe its resources, management experience, and organizational capacity. This will involve providing financial information about the project and an overview of the investors and strategic partnerships involved. The application must also explain any suspensions in the project's operation.

HHS will communicate the results of its evaluation to the IRS, which will determine which projects certified by HHS have the greatest potential to (1) create high quality high-paying jobs in the U.S. and (2) advance U.S. competitiveness in the fields of life, biological, and medical sciences. The IRS will combine the HHS evaluation with its own and certify an amount of qualified investment for each successful applicant. Generally each taxpayer is limited to $5 million (aggregate) in credits under the program.

In approximately one month, the IRS will issue Form 8942 and the form PIM Until then, this alert provides the roadmap for gathering information and assessing eligibility with respect to this valuable credit or grant. If you would like to discuss how this information may affect your business, or have any other BioPharma, tax planning, or estate planning questions, please contact Ryan Udell (215.864.7152), Mike Mentzel (215.864.7156), Kevin Koscil (215.864.6827), Scott Borsack (215.864.7048), or Bill Hussey (215.864.6257).

IRS Circular 230 Notice: *To ensure compliance with certain regulations promulgated by the U.S. Internal Revenue Service, we inform you that any federal tax advice contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, by any taxpayer for the purpose of (1) avoiding tax-related penalties under the U.S. Internal Revenue Code, or (2) promoting, marketing or recommending to another party any tax-related matters addressed herein, unless expressly stated otherwise.*