

WSGR ALERT

MAY 2010

TREASURY DEPARTMENT ISSUES GUIDANCE ON THERAPEUTIC DISCOVERY PROJECT TAX CREDIT AND GRANT PROGRAM FOR SMALL EMPLOYERS

The recent Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (PPACA), established a limited-time federal tax credit and grant program for certain investments incurred in 2009 and 2010 by small employers for qualifying therapeutic discovery projects (QTDP Credit and Grant Program). This health care reform bill authorized up to \$1 billion in investment tax credits and cash grants through the QTDP Credit and Grant Program to life sciences companies with no more than 250 employees to defray the costs of biomedical research. Because the total amount of tax credits and grants may not exceed \$1 billion, eligible companies must apply for and be selected to receive such credits or grants through a competitive certification process.

Rules and related guidance regarding the program are detailed in IRS Notice 2010-45, which establishes the application process, timetable, and selection criteria for the Treasury Department's award of certifications under the QTDP Credit and Grant Program. **To compete for a credit or grant allocation, companies must file an application for certification of their qualified investment in a qualifying research project by July 21, 2010.**

The following links can be used to access IRS Notice 2010-45 and the related Treasury fact sheet, respectively: <http://www.irs.gov/pub/irs-drop/n-10-45.pdf> and <http://www.ustreas.gov/press/releases/reports/5.21.10%20therapeutic%20discovery%20fact%20sheet.pdf>.

This WSGR Alert is solely a summary of the guidance. You are advised to carefully review

IRS Notice 2010-45 for a complete understanding of the guidance.

Background

Section 9023 of the PPACA created Section 48D of the Internal Revenue Code of 1986 (IRC), providing for a new tax credit equal to 50 percent of an eligible taxpayer's qualified investments with respect to a qualifying therapeutic discovery project. The total amount of credits available under Section 48D is limited to \$1 billion, to be awarded to eligible recipients for certified investments in projects selected by the Internal Revenue Service (IRS) together with the Department of Health and Human Services (HHS), based on specified criteria. Section 9023(e) of the PPACA provides that a company that is awarded the U.S. tax credit may elect to receive a cash grant in lieu of the tax credit, enabling companies that have no U.S. tax liability to also benefit from the QTDP Credit and Grant Program.

I. Eligible Companies

QTDP Credits and Grants are only available to companies with no more than 250 employees at the time the application is submitted. All employees within a controlled or affiliated group of entities are taken into account when calculating an applicant's number of employees, although "leased employees" are not included in the calculation. Subject to the foregoing, both private companies, including venture-capital-funded companies, and public companies are eligible for the QTDP Credit and Grant Program.

II. Qualifying Projects

To be eligible for consideration, qualifying therapeutic discovery projects must be designed to:

- treat or prevent diseases or other conditions by conducting pre-clinical activities, clinical trials and clinical studies, or by carrying out research protocols, for the purpose of securing approval of a drug product under Section 505(b) of the Federal Food, Drug and Cosmetic Act or a biologic product under Section 351(a) of the Public Health Service Act;
- diagnose diseases or conditions;
- determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions; or
- develop a product, process or technology to further the delivery or administration of therapeutics.

III. Selection Criteria

The legislation requires that awards be directed to projects that show reasonable potential to:

- result in new therapies to either (i) treat new areas of unmet medical need, or (ii) prevent, detect or treat chronic or acute diseases or conditions;
- reduce long-term health care costs in the United States; or

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- significantly advance the goal of curing cancer within the next 30 years.

Moreover, in selecting award recipients, the IRS will take into consideration which projects have the greatest potential to:

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

In making this determination, the IRS will take into consideration to what extent a project:

- 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
- is expected to lead to the construction or use of a contract production facility in the U.S. in the next five years.

Consequently, applicants should address in their application both the health care and broader economic benefits of their therapeutic development project. Since applications will be reviewed by both HHS and IRS personnel with varying levels of knowledge regarding life science technologies and products, project summaries should clearly communicate the significance and likelihood of success, and potential benefits of the project to both laypersons and industry experts.

IV. Qualifying Expenditures

Generally speaking, a “qualified investment” includes costs paid or incurred in a taxable year beginning in 2009 or 2010 for expenses necessary for and directly related to the conduct of a qualifying therapeutic discovery project, **excluding**:

- compensation for the CEO;
- if the company is a public reporting company, compensation for the four highest-paid officers other than the CEO;

- interest expenses;
- facility maintenance expenses (mortgage or rent payments, insurance payments, utility and maintenance costs, and costs of employment of maintenance personnel);
- indirect costs (such as general and administrative costs) associated with administrative, service, or support departments (such as personnel, accounting, data processing, security, legal, etc.); and
- other excluded expenses, as may be determined by the Secretary of the Treasury.

The IRS may certify up to a maximum of \$10 million of qualified investment per applicant (representing a maximum QTDP Credit or Grant amount of \$5 million per company).

V. Grant in Lieu of Tax Credit

Recipients of certifications under the QTDP Credit and Grant Program may elect to receive a cash grant in lieu of the tax credit, enabling companies that do not have U.S. tax liability to also benefit from the program.

However, QTDP Grants in lieu of the credit are not available to the following applicants:

- federal, state, or local governments, or any political subdivision, agency, or instrumentality thereof;
- tax-exempt organizations described in Section 501(c) of the IRC;
- clean renewable energy bond lenders, cooperative electric companies, or governmental bodies; or
- any partnership or other pass-through entity with a member, equityholder, or holder of a profit interest that is an ineligible entity listed above.

The guidance provides that any entity (including entities with U.S. tax liability) other than those listed above may elect to receive either a tax credit or a grant with respect to its

certified qualified investment for a taxable year. Applicants interested in receiving a grant in lieu of the credit must so indicate in their application on (yet to be released) IRS Form 8942. Even after filing an application, an applicant can later elect to receive a grant in lieu of the credit by filing an amended Form 8942. Such amended Form 8942 must be filed (a) by September 30, 2010, in order to elect a grant in lieu of credit with respect to 2009 taxable year investments, and (b) by the due date (including any extensions) of the applicant’s 2010 taxable year’s tax return, in order to elect to receive a grant with respect to 2010 taxable year investments.

Amounts received pursuant to a QTDP Grant are not taxable as federal income.

VI. Program Timeline and Application Process

In June 2010, the IRS will open a primary allocation round to issue certifications for qualified investments made in taxable years beginning in either 2009 or 2010. If any portion of the \$1 billion available under the QTDP Credit and Grant Program remains unallocated after this primary allocation round, the IRS may conduct one or more additional allocation rounds.

- **Application Deadline** – Applications for the primary 2009-2010 allocation round can be filed as soon as the IRS releases Form 8942, “Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program” (Form 8942), which is expected to be no later than June 21, 2010. Applications must be submitted and postmarked no later than July 21, 2010. The timing of when an application is submitted during this period will not affect its likelihood of funding. If an applicant seeks to claim the QTDP Credit or Grant with respect to more than one qualifying therapeutic development project, it should file a separate application for each project. An application may request certification of a project’s costs incurred in taxable years beginning in 2009, 2010, or both.

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- Contents of Application – A complete application consists of three parts: (1) a completed Form 8942, (2) a Project Information Memorandum satisfying the requirements set forth in Appendix A to IRS Notice 2010-45, and (3) if the applicant consents to public disclosure of the type of its therapeutic project, the consent form provided in Appendix B to IRS Notice 2010-45. Form 8942 will require an applicant to describe its qualified investment amount in the project and the current and projected jobs attributable to the project. The Project Information Memorandum must contain specified statements of the scientific rationale and support for the project's potential, the stage of development of the project, and the financial and organizational resources available to bring the project to successful completion, and must comply with detailed format rules, including strict word limits for each statement.
- Preliminary Review of Applications – By September 30, 2010, the IRS will complete a preliminary review of all timely submitted applications to confirm that each applicant has no more than 250 employees and to ensure that each application is complete. The IRS and HHS may decline to consider incomplete applications.
- HHS and IRS Evaluation of Applications – HHS will evaluate all applications that pass the preliminary review to ensure that certifications are only awarded to projects that (1) satisfy the definition of a qualifying therapeutic development project, and (2) show reasonable potential to (a) result in new therapies to treat areas of unmet medical need or prevent, detect, or treat chronic diseases or conditions, (b) reduce long-term health care costs, or (c) advance the goal of curing cancer. In order for a project to be certified, the IRS must identify it as among those projects with the greatest potential to create quality jobs in the U.S. and advance U.S. competitiveness in the biomedical

sciences. Based on their review, the IRS and HHS will determine which applications have met the certification requirements and will be approved.

- Allocation of Certified Investment Amounts – The IRS will then determine the amount of qualified investment that it will certify for each approved application. Initially, the IRS will allocate the \$1 billion of available credits and grants equally (pro-rata) among all the certified projects. However, the amount of the certified qualified investment for any project cannot exceed the qualified investment documented in the project's application, and the IRS will not certify more than \$10 million in qualified investments for any company. Any pro-rata certification amounts that remain unused due to these caps will be re-allocated equally among all certified projects whose initial allocations reflected only a portion of their documented qualified investments. As a result, depending on the number of applications that successfully meet the certification requirements and the documented qualified investments associated with those applications, the IRS may certify all or just a portion of an award recipient's qualified investment amount.
- Notification of Awards – Applicants will be notified by letter by October 29, 2010 whether their application for certification has been approved. For each certified project, the acceptance letter will state the amount of the credit or grant allocated to the project.
- Timing of Grant Fund Payments – The Treasury Department must authorize payment to grant recipients of QTDP Grant funds with respect to 2009 taxable year investments by the later of October 29, 2010, or 30 days after the date the qualified investment is made. QTDP Grant funds with respect to 2010 taxable year investments will be paid to grant recipients within 30 days after the later of the start of the applicant's 2011

taxable year, or the date the grant election is filed.

- Public Disclosure of Allocations and Projects – Upon certification of a project, the IRS will publicly disclose the identity and amount of credit/grant awarded to each recipient. In addition, the IRS will publish the type and location of all projects that receive a QTDP Grant. The IRS will also publish the type and location of each project awarded a QTDP Credit that included as part of its application a specified consent.

VII. Practical Tips for Applicants

- Maximum Amount of Award – The IRS will not certify more than \$10 million in qualified investments for any company and will not issue more than \$5 million in tax credits under the program to any company, regardless of the number of applications the company files. The maximum \$5 million credit is not assured for any company, as the actual tax credit awarded will depend on the number of applications that are approved and the qualified investments certified.
- Confidentiality of Application Materials – Under the Freedom of Information Act (FOIA), QTDP Credit and Grant Program applications will be subject to public access. To protect trade secret, confidential, or privileged information contained in an application from disclosure under FOIA, an applicant should assert a claim of exemption from FOIA under 5 U.S.C. §552(b)(4) on the first page of their application and should submit two copies of the application: one complete original copy and another copy with confidential information redacted.
- Eligibility of Medical Devices – To qualify as a QTDP, a medical device development project must concern a device designed to further the delivery or administration of either a drug as

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defined in Section 201(g) of the Federal Food, Drug and Cosmetic Act (FFDCA) or a medical device as defined in Section 201(h) of the FFDCA. For example, projects focused on drug-eluting stents or infusion pumps would constitute QTDPs. However, the development of a medical device that does not further the delivery or administration of a drug (as defined in Section 201(g) of the FFDCA) or medical device (as defined in Section 201(h) of the FFDCA) would not be a QTDP. The FFDCA Section 201(h) definition of "medical device" is complex and does not include all types of medical devices. Accordingly, companies should consult with their regulatory advisors to confirm the eligibility of their medical device projects for the QTDP Credit and Grant Program.

- **Eligibility of Diagnostics** – The QTDP definition encompasses any project focused on a diagnostic product that diagnoses a disease or condition, regardless of whether it determines molecular factors or is a molecular diagnostic. Thus, a project focused on point of care diagnostics for infectious agents would constitute a QTDP.
- **Ineligible Drugs and Therapeutic Products** – Projects focused on the development of generic drugs (approved under Section 505(j) of the FFDCA rather than Section 505(b)), biosimilar products (approved under Section 351(k) of the PHSA instead of Section 351(a)), or dietary supplements (which generally are not the subject of a new drug or biologic license application) would not constitute QTDPs and are thus ineligible for a QTDP Credit or Grant.
- **Application of Selection Criteria** – Relatively little detail has been provided in the IRS guidance regarding how the specified selection criteria will be applied by the IRS and HHS in selecting projects for approval. However, the following specifics are contained in the IRS guidance: (1) for a project to be considered a "new therapy," it must be

novel and thus cannot be in the same class as existing therapies, unless it is expected to offer a significant enhancement in safety or effectiveness; (2) "unmet medical needs" are not defined, but novel influenza vaccine technologies, broad spectrum anti-viral medications, novel antibiotics, and platform vaccine technologies are provided as examples of unmet medical needs; and (3) applicants seeking to demonstrate that a project will reduce long-term health care costs in the U.S. should (a) describe how their project will lead to actual cost reductions (not just substituting one cost for another) and the basis of this determination, and (b) provide a reasonable estimate of savings and demonstrate potential to achieve these savings.

VIII. Important Tax Implications for QTDP Credit/Grant Recipients

No Double-Dipping

The QTDP Credit and Grant rules contain provisions to deny double tax benefits for the same expense. Thus, expenses taken into account for the QTDP Credit or Grant cannot be included to determine the research credit or orphan drug credit for the taxable year, although expenses that are also "qualified research expenses" for purposes of the research credit are included in the taxpayer's base period research expenses to calculate its research credit for subsequent taxable years.

A complex set of rules applies to disallow the deduction of expenses that are included in the calculation of the QTDP Credit or Grant. These rules essentially operate to deny deductions to the extent of the related credit or grant amount received. First, 50 percent of expenses that are part of the qualified investment (other than expenses that would be included in the computation of the research credit or the orphan drug credit for the taxable year) cannot be deducted. Second, expenses that would be included in the computation of the research credit or the orphan drug credit for the taxable year cannot be deducted to the extent that the QTDP Credit or Grant for the taxable year

exceeds the sum of (i) 50 percent of the other expenses plus (ii) the amount of the basis reduction in depreciable property required as a result of taking the QTDP Credit or Grant.

In addition, (i) if a QTDP Credit or Grant is allowed for an expense related to depreciable property, the basis of the property (and thus the depreciation deductions) is reduced by the amount of the credit or grant; and (ii) a QTDP Credit or Grant is not allowed for any investment for which bonus depreciation is allowed under IRC Sections 168(k)(repealed after 2009), 1400L(b)(1)(New York Liberty Zone Property), or 1400N(d)(1)(Gulf Opportunity Zone Property).

Limitations on Use of the QTDP Credit

The QTDP Credit is part of the investment credit, which in turn is part of the general business credit under IRC Section 38. The maximum amount of the general business credit that a taxpayer can use in a taxable year is the excess of the taxpayer's net income tax for the year (which is the sum of its regular tax and alternative minimum tax (AMT) for the year reduced by certain credits, including the foreign tax credit) over the greater of (i) the taxpayer's tentative minimum tax or (ii) 25 percent of the taxpayer's regular tax liability in excess of \$25,000. As a result of this limitation, taxpayers cannot generally use the general business credit to reduce their AMT liability. Although certain components of the general business credit can be used to reduce a taxpayer's AMT, the QTDP Credit cannot be used to reduce AMT. The amount of a taxpayer's general business credit that cannot be used in the year it is earned because of the above limitation may be carried back one taxable year and carried forward 20 taxable years, in each case subject to limitation on its use. Because the QTDP Credit is available only to taxable years beginning in 2009 or 2010, it cannot be part of the amount of the general business credit that is carried back to a taxable year beginning before 2009.

State Tax Treatment of QTDP Grants

As mentioned above, IRC Section 48D(f)(3) provides that a QTDP Grant is not included in

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the recipient's gross income. Although many states automatically conform their tax law with changes to the IRC, many states do not. California, for example, has conformed only to the IRC as it existed on January 1, 2009 (and then only to portions of the IRC as it then existed). Because IRC Section 48D(f)(3) was not enacted until March 2010, and because it has not otherwise been incorporated into California tax law, a QTDP Grant, in the absence of legislation, will likely be subject to tax in California.¹ Even if a QTDP Grant is subject to state income tax, it nonetheless may be more valuable to an applicant (especially an applicant with substantial losses) than a QTDP Credit.

Recapture of QTDP Credits and Grants

QTDP Credits and Grants are subject to recapture in the event of certain sales of a qualifying project, sales of certain interests in the entity controlling a qualifying project, or in the event a certified project investment ceases to be a qualified investment.

For Further Information: BIO Webinar on May 26, 2010

BIO, the Biotechnology Industry Organization, will host a webinar for its members on Wednesday, May 26, at 1 p.m. Eastern Time to review the guidance contained in IRS Notice 2010-45 and answer questions about the QTDP Credit and Grant Program. This webinar is open to all BIO members and dial-in information can be found at www.members.BIO.org.

For more information or any general questions concerning the QTDP Credit and Grant Program, please contact any member of Wilson Sonsini Goodrich & Rosati's life sciences practice. For any tax-related questions concerning the QTDP Credit and Grant Program, please contact Michael Faber or Ivan Humphreys in Wilson Sonsini Goodrich & Rosati's tax practice.



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¹ The California Franchise Tax Board took this position with respect to grants made in lieu of energy credits under Section 1603 of the American Recovery and Reinvestment Act of 2009. California tax law was recently amended to specifically provide that those Section 1603 grants are not taxable in California. Similar legislation may be required to exclude QTDP Grants from income in California.