

New Tax Credits or Grants Available Soon for Developers of Therapeutic Medical Products

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The Patient Protection and Affordable Care Act of 2010, enacted on March 23, established a new \$1 billion Qualifying Therapeutic Discovery Project program, with a tax credit (“QTDP Credit”) for investments in 2009 and 2010 by small and mid-size companies developing therapeutic medical products. Companies qualifying for the QTDP Credit may apply for a grant instead (the “QTDP Grant”). By May 21st the Secretary of the Treasury must issue the form of application and criteria guidelines for the program. Recipients will receive a credit or grant for 50% of their qualifying investments. The application process is likely to be competitive, so now is the ideal time for companies to evaluate their eligibility and prepare for the application process.

Who Qualifies

The QTDP program is limited to companies with no more than **250 employees** at the time of the application. Commonly controlled and affiliated employers will be aggregated together and treated as a single employer for purposes of applying the 250-employee limitation. A company will not qualify for a QTDP Grant if it is (a) a federal, state or local governmental entity, (b) a tax-exempt organization, or (c) a partnership or other pass-thru entity which has one or more owners which are either governmental entities or tax-exempt organizations.

Qualifying Therapeutic Discovery Project

A qualifying therapeutic discovery project includes any project which is designed to:

- treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials and clinical studies, or carrying out research protocols,

- diagnose diseases or conditions or to determine molecular factors related to disease 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.

Qualified Investments

Qualified investments include expenses incurred in 2009 and 2010 that were necessary for, and directly related to, the conduct of a qualifying therapeutic discovery project. Certain expenses are specifically excluded, including: (1) salaries of certain highly compensated employees; (2) interest expenses; (3) facility maintenance expenses; (4) certain indirect costs; and (5) other expenses to be identified by the Secretary of the Treasury ("Secretary").

Amount of QTDP Credit and QTDP Grant

The QTDP Credit will equal 50% of the "qualified investment" in any tax year with respect to a "qualifying therapeutic discovery project."

The QTDP Grant will equal 50% of the "qualified investment" in any tax year with respect to a "qualifying therapeutic discovery project." A QTDP Grant will not be includable in a company's taxable income.

A variety of rules will limit the ability of a company that receives either the QTDP Credit or the QTDP Grant to receive a "double benefit." First, a company that receives the QTDP Grant will not be eligible for the QTDP Credit. Further, a company that receives either the QTDP Credit or the QTDP Grant will not be eligible to claim bonus depreciation, research credits and other tax benefits for the same expenditures. Finally, the tax basis of the property must be reduced by the amount of the QTDP Credit or QTDP Grant.

QTDP Program Criteria

By no later than May 21, 2010, the Secretary, in consultation with the Secretary of Health and Human Services, is tasked with establishing the QTDP program to consider and award certifications for qualifying investments eligible for the QTDP Credit and QTDP Grant. The Secretary will publish a form of application accompanied by criteria for determining which qualified therapeutic discovery projects should qualify for the program, taking into consideration only those projects that show reasonable potential (1) to result in new therapies (a) to treat areas of unmet medical need or (b) to prevent, detect or treat chronic or acute diseases and conditions; (2) to reduce long-term health care costs in the U.S.; **or** (3) to significantly advance the goal of curing cancer within the next 30 years. In addition, the Secretary must take into consideration which projects have the greatest potential to (1) create and sustain 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 "QTDP Criteria").

Application for Certification

A company will not be eligible for the QTDP Credit or the QTDP Grant unless its qualified investments have been certified by the Secretary. To receive certification, a company will be required to submit an application to the Secretary. The application may include both 2009 and 2010 qualified investments. The Secretary is to approve or deny the application within 30 days.

Selection Process

It is not possible to predict the content of the application and the selection process with any certainty. But given that the QTDP program is limited to \$1 billion, the selection process is likely to be competitive. The nature of the competition is less clear. The competition could be based entirely on timing—the applications will be certified based on date of receipt until the QTDP program is exhausted. The legislative mandate to the Secretary to develop the QTDP Criteria make it more likely that the competition for awards will be based—at least in part—on satisfying these QTDP Criteria.

In establishing the QTDP program, the Treasury Department may take a similar approach to the one it used in 2009 in establishing the program for the award of Qualifying Advanced Energy Project Credit under Section 48C (the “**Energy Credit**”). In that case, the department issued the form of application and guidance about two months prior to the deadline for filing. The application required extensive information about a number of factors, including information to evaluate the cost and the energy savings produced by the clean energy technology and the number of jobs created. Once submitted, the applications were reviewed and scored by the Department of Energy, ranked based on points, and the Energy Credits were allocated based on ranking. A number of applicants did not receive any award.

Although there are similarities between the Energy Credit program and the QTDP program, there are also a number of differences. In addition to the technology involved and the statutory criteria mandated for awarding the credits, the Energy Credit program placed no limits on the size of the applicant. Further, due to the statutory requirement that an application be approved or denied within 30 days, it is likely that a less rigorous review process will be involved in the QTDP program. Information about the Energy Credit program can be found at <http://www.energy.gov/recovery/48C.htm>.

Planning Steps

Any company satisfying the threshold requirements for the QTDP program should monitor the issuance of the application and guidance by the Secretary. As noted, the deadline for this guidance is May 21, 2010. In the meantime, a company should collect the documentation regarding its qualifying therapeutic discovery project that is likely to be required, including (i) documentation that the project meets the QTDP Criteria (e.g., evidence of a new therapy, reduction in long-term health care costs, or advancing a cure for cancer within a 30-year period, and evidence of job creation), and (ii) documentation of the qualified investments made or projected to be made in 2009 and 2010.

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

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