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Tax Credits and Grants Available for Certain Pharmaceutical, Biotechnology, and Other Healthcare Companies: Applicants Should Prepare Now

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Pharmaceutical, biotechnology, and other healthcare companies with 250 or fewer employees may be eligible to take advantage of a new tax credit and grant program included as part of the Patient Protection and Affordable Care Act of 2010 signed into law on March 23, 2010. The Act added new Section 48D to the Internal Revenue Code, which outlines the qualifications and standards for eligibility under a program referred to as the "therapeutic discovery project tax credit and grant program." A total of $1 billion is available under the discovery program for certain costs incurred or paid by eligible companies in taxable years beginning in 2009 and 2010 in connection with "qualifying therapeutic discovery projects."

The tax credit is equal to 50 percent of the amount of certain costs incurred or paid in connection with a qualifying project by an eligible company. Eligible companies that do not currently have taxable income may elect to receive a direct cash grant in lieu of the tax credit in an amount equal to 50 percent of these costs. The discovery program will be managed by the U.S. Secretary of the Treasury and presents a significant financial opportunity for a number of pharmaceutical, biotechnology, and other healthcare companies.

Criteria for Qualifying Therapeutic Discovery Project

The company seeking the tax credit or grant must have 250 or fewer employees. Costs must be for the 2009 and 2010 tax years and must be paid or incurred in connection with a "qualifying project." A qualifying project under Section 48D is defined as a project designed to:

- treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research protocols, for the purpose of securing approval of a product under Section 505(b) of the Federal Food, Drug, and Cosmetic Act or Section 351(a) of the Public Health Service Act;
- diagnose diseases or conditions or 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.

Types of Companies that May Qualify

A few examples of the types of companies that may be eligible for the credit or grant are:

- biotech or pharma companies that invest significant resources in pre-clinical or clinical studies;
- biotech companies engaged in development of diagnostic assays or applications to advance therapeutics and treatments;
- companies engaged in basic or applied research that may ultimately contribute to curing cancer or other diseases and conditions; and
- companies studying gene therapy or conducting stem cell research.

Selection Criteria

Not all companies that meet the eligibility standards will receive the credit. The new law mandates that the Secretary of the Treasury take into consideration only those projects that show reasonable potential to:

- result in new therapies to treat areas of unmet medical need;
- prevent, detect, or treat chronic or acute diseases and conditions;
- reduce long-term health care costs in the U.S.; or
- significantly advance the goal of curing cancer within a 30-year period.

As part of the selection process, Section 48D also instructs the Secretary of the Treasury to 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 life, biological, and medical science fields.

The Application Process: How to Prepare

To be considered for the discovery program, eligible companies will be required to submit a formal application. Although the Secretary of the Treasury has not yet released the application instructions (it has until May 22, 2010 to do so), we believe there are several steps that companies can take now to prepare to apply for a tax credit or grant. Since the discovery program is likely to be oversubscribed and the application process is expected to be highly competitive, we recommend that interested companies begin to evaluate their eligibility for the program immediately and start collecting and evaluating information expected to be required for the application as soon as possible.

It is likely that the Secretary of the Treasury will require that applicants provide a detailed overview and description of each project for which they are seeking a tax credit or grant, including arguments and supporting documentation demonstrating that the project meets the criteria for a qualifying project discussed above. Accordingly, companies should evaluate each potentially eligible project to determine those that are most likely to satisfy the criteria under Section 48D and prioritize their resources and time to gathering information related to their most viable projects first.

In addition, the application will likely require applicants to certify that they have 250 or fewer employees. Importantly, under Section 48D, the measurement date for determining the number of employees is the date the application is submitted, not the date that the costs for the qualifying project were incurred or paid nor the date the credit or grant may be approved. Employees that are within a controlled or affiliated group will generally be included in the calculation. As such, companies that have joint operating agreements or other arrangements with other companies will need to consider whether such agreements or arrangements may make them ineligible to apply for a tax credit or grant under the discovery program.

It is also likely that the application will request detailed financial information about each project, including an itemized list of costs incurred or paid. Applicants also may be required to demonstrate and/or certify that the costs paid or incurred were "necessary for and directly related to" the conduct of the project. Notably, Section 48D specifically excludes certain costs from the discovery program, including:

- compensation for employees described under Section 162(m)(3) of the Internal Revenue Code (certain highly compensated executive officers);
- interest expenses;
- facility maintenance expenses; and
- service costs under Section 263A of the Internal Revenue Code.

The Secretary of the Treasury has the right to exclude other costs from the program as well. Companies who intend to apply for the discovery program should begin working with their accountants and financial advisors as soon as possible to determine which costs may be eligible for a tax credit or grant under the program.

Within 30 days from the date an application is submitted, the Secretary of the Treasury must certify and award a project, decline the award or request additional information or clarification about the project. Awarded grants will not be included in a recipient's taxable income.

Conclusion

While it is uncertain at this point whether the credits and grants under the therapeutic discovery project tax credit and grant program will be available on a "first-come, first-served" basis, the application process is nevertheless likely to be highly competitive and selective. Submitting thorough documentation as early as possible may be critical in determining whether an applicant receives a tax credit or grant under the discovery program. Therefore, we strongly recommend that interested companies begin evaluating their eligibility to participate in the program, and begin preparing arguments, financial information, and other supporting materials for each potential qualifying project to ensure they will be prepared when the Secretary of the Treasury finally announces the application requirements and procedures.

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